

US3592111 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:38:19

All time stamps listed in this document are displayed in GMT

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Form: Participant Creation

Generated On: 26 Nov 2020 09:38:19

[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 09:38:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 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 09:38:19

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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 09:38:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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 09:38:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

Condition	HEARING LOSS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

Condition	MYOPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 1955
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 1955
Start Year (derived)	1955
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

Condition	HYPEROPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

Condition	CHRONIC COUGH DUE TO POST NASAL DRAINAGE
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

Condition	FIBROCYSTIC BREAST DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

Condition	OSTEOARTHRITIS LEFT KNEE
Start date (dd MMM yyyy)	UN DEC 2014
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)	DEC 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:53 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:53
Height (<i>xxx.x</i>)	168.0 cm
Weight (<i>xxx.x</i>)	76.5 kg
BMI (<i>xxx.x</i>)	27.10459 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 09:38:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1997

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	SUBJECT GOES TO CHURCH ONCE A WEEK AND GOES TO THE GROCERY STORES AT LEAST ONCE A WEEK AND VOLUNTEERS AT A SCHOOL WITH CHILDREN ONCE A WEEK.

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 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 09:38:19

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185380

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 09:38:19

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 09:38:19

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)	10 AUG 2020
Time of assessment (00:00-23:59)	17:53 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:53
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 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 09:38:19

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)	10 AUG 2020
Time of assessment (00:00-23:59)	19:38 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:38
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	108 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

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 09:38:19

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)	10 AUG 2020
What was the treatment time? (00:00-23:59)	19:07 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 19:07
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 09:38:19

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

10 AUG 2020

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

12:30 (24 HR)

Collection date and time (derived)

10 AUG 2020 12:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:19

Collection date (<i>dd MMM yyyy</i>)			10 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	16:40	10 AUG 2020 16:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

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 09:38:19

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

97.5 °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

10 AUG 2020 19:41

PC Open Date & Time

10 AUG 2020 19:27

PC Close Date & Time

10 AUG 2020 21:57

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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**

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 10 AUG 2020 22:52

PC Close Date & Time 11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

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

12 AUG 2020 13:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

97.7 °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

13 AUG 2020 14:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

97.9 °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

14 AUG 2020 14:07

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

15 AUG 2020 12:27

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

16 AUG 2020 14:44

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

10 AUG 2020 19:42

PC Open Date & Time

10 AUG 2020 19:27

PC Close Date & Time

10 AUG 2020 21:57

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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 ☐

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.**

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

PC Open Date & Time

10 AUG 2020 22:52

PC Close Date & Time

11 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

11 AUG 2020 17:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

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

12 AUG 2020 13:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

13 AUG 2020 14:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

14 AUG 2020 14:08

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

15 AUG 2020 12:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

16 AUG 2020 14:44

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:43
PC Open Date & Time	10 AUG 2020 19:27
PC Close Date & Time	10 AUG 2020 21:57

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 22:52

PC Close Date & Time

11 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	11 AUG 2020 17:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	12 AUG 2020 13:39
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	13 AUG 2020 14:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	14 AUG 2020 14:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	15 AUG 2020 12:28
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	16 AUG 2020 14:45
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

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

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 10:58
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 11:47
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 SEP 2020

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

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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)	7 SEP 2020
What was the treatment time? (00:00-23:59)	11:16 (24 HR)
Treatment Date and Time (derived)	7 SEP 2020 11:16
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

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	7 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:05 (24 HR)
Collection date and time (derived)	7 SEP 2020 11:05

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:19

Collection date (dd MMM yyyy)			7 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	7 SEP 2020 11:06
Nasopharyngeal Swab 2	No		

US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 11:49

PC Open Date & Time

07 SEP 2020 11:36

PC Close Date & Time

07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

97.9 °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

08 SEP 2020 09:05

PC Open Date & Time

07 SEP 2020 15:01

PC Close Date & Time

08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

97.0 °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

09 SEP 2020 09:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

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**

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 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

97.5 °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

10 SEP 2020 14:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

96.5 °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

11 SEP 2020 13:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

97.7 °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

12 SEP 2020 13:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

13 SEP 2020 16:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

07 SEP 2020 11:50

PC Open Date & Time

07 SEP 2020 11:36

PC Close Date & Time

07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

08 SEP 2020 09:06

PC Open Date & Time

07 SEP 2020 15:01

PC Close Date & Time

08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

09 SEP 2020 09:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

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 ☐

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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

10 SEP 2020 14:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

11 SEP 2020 13:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

12 SEP 2020 13:59

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

13 SEP 2020 16:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 11:50
PC Open Date & Time	07 SEP 2020 11:36
PC Close Date & Time	07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:06
PC Open Date & Time	07 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	09 SEP 2020 09:07
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

		Yes ☐
PC Time stamp		
PC Open Date & Time		09 SEP 2020 12:00
PC Close Date & Time		10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	10 SEP 2020 14:50
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	11 SEP 2020 13:16
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

Yes ☐	
PC Time stamp	13 SEP 2020 16:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:28 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 15:28
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

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.

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	6 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:50 (24 HR)
Collection date and time (derived)	6 OCT 2020 15:50

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 07:37:29

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

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

Date and time of submission

19 OCT 2020 12:24:26

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 16:18:07

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-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	07 NOV 2020 16:18:41
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-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	14 NOV 2020 18:40:26
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 16:43:32
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 FEB 2021 00:01

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21 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAR 2021 00:01

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07 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAR 2021 00:01

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14 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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°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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2022 00:01

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23 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 FEB 2022 00:01

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13 FEB 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

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16 FEB 2022 00:01

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20 FEB 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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

Date and time of submission

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02 MAR 2022 00:01

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06 MAR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 MAR 2022 00:01

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20 MAR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 APR 2022 00:01

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10 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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13 APR 2022 00:01

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17 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 APR 2022 00:01

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24 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2022 00:01

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17 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2022 00:01

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24 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592111

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:38:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592111

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

AEID	USA-US103-2020-MRNA-1273-P30 1000005
Adverse event	PERFORATED DIVERTICULITIS
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)	03 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)	
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)	05 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	343 of 1755

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

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	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	

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

CRC WAS NOTIFIED OF
SUBJECTS HOSPITALIZATION
UPON RECEIVE MESSAGE
FROM THE WEEKEND. TC TO
SUBJECT MADE AT 0805 AND
0840 TO OBTAIN MORE
INFORMATION. SUBJECT IS
CURRENTLY HOSPITALIZED AT
ST FRANCIS HOSPITAL. PER
SUBJECT REPORT SHE WAS
EXPERIENCING ABDOMINAL
PAIN ON 03NOV2020 AND
PRESENTED TO ER AT
APPROXIMATELY 0330. DURING
THAT VISIT A CT SCAN WAS
PERFORMED AND SUBJECT
WAS TOLD SHE HAD
DIVERTICULITIS WITH
PERFORATION. SHE WAS GIVEN
MORPHINE AND DILAUDID FOR
PAIN CONTROL IN THE ER.
SUBJECT STATED THAT THEY
SENT HER HOME FROM ER
ABOUT 2 HOURS LATER WITH
AUGMENTIN AND
HYDROCODONE AND
INSTRUCTIONS TO FOLLOW UP
WITH PCP. SUBJECT WAS NOT
ABLE TO GET INTO HER PCPS
OFFICE FOR A FOLLOW APPT
UNTIL AFTERNOON ON
THURSDAY 05NOV2020.
DURING THAT VISIT SUBJECT
PCP FELT IT NECESSARY TO
DIRECTLY ADMIT SUBJECT TO
THE HOSPITAL FOR FURTHER
ASSESSMENTS AND

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

TREATMENT. REPEAT CT SCAN
DONE UPON ADMISSION ALSO
IDENTIFIED AN ABSCESS IN
THE BOWEL. SUBJECT
CONTINUES TO BE ADMITTED
TO HOSPITAL SHE IS ON A
CLEAR LIQUID DIET AND
RECEIVING MEDICATION FOR
PAIN MANAGEMENT AND
NAUSEA CONTROL. PER
SUBJECT THE CURRENT PLAN
IS TO MONITOR FOR
IMPROVEMENTS/DECLINE
WHILE SHE RECEIVES IV
ANTIBIOTICS AND IV FLUIDS.,
NO SURGERY HAS BEEN DONE
AND THERE ARE NO PLANS
FOR SURGERY AT THIS TIME.
WILL OBTAIN MEDICAL
RECORDS FOR MORE PRECISE
INFORMATION. ADDITIONAL
DURING TC SUBJECT
CONFIRMED THAT SHE HAS NO
KNOWN HISTORY OF
DIVERTICULITIS OR ANY
OTHER GI CONDITION PRIOR
TO THIS.

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

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

AEID	
Adverse event	COLON ABSCESS
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)	05 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:19

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

Yes ☒

No ☐

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	TELMISARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	LIOTHYRONINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	7.5
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

	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)		1 MAY 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☐ No ☒
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1
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 ☐

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	VITAMIN D
Prophylaxis	Yes ☐ No ☒
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	400
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	PHENYLEPHRINE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC COUGH
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	FEXOFENADINE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC COUGH
Dose per administration	180
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 ☐

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

	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)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:19

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:38:19

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 ☐

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

SAEID	USA-US103-2020-MRNA-1273-P301000005
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:19

SAEID	USA-US103-2020-MRNA-1273-P301000005
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	10/NOV/2020 17:23
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

US3592111 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592111

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3592111'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 22:49:10

US3592111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 00:13:49

US3592111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 22:49:11

US3592111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 00:13:49

US3592111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 00:13:49

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 22:49:12

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Age](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '73'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:19

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 22:49:11

US3592111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:12:53

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:26
Data point term sent to Coder	System	19 Aug 2020 18:14:07
User entered 'hearing loss bilateral'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2014'	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:36:25
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	29 Sep 2020 19:21:46
Query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data has been updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:20:55
Data point term sent to Coder	System	29 Sep 2020 19:20:20
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 19:20:17
User entered 'MYOPIA bilateral' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:20:17
User opened query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 15:15:03
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Aug 2020 18:15:26
Data point term sent to Coder	System	19 Aug 2020 18:14:10
User entered 'myopia'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 1955'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 1955'	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '1955'	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:36:42
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:23:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	29 Sep 2020 19:23:51
Data point term sent to Coder	Coder Import (b) (4)	29 Sep 2020 19:22:23
Query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data has been updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:21:47
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 19:21:32
User entered 'HYPEROPIA bilateral' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:21:32
User opened query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 15:15:13
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Aug 2020 18:15:43
Data point term sent to Coder	Coder Import (b) (4)	19 Aug 2020 18:15:13
User entered 'hyperopia'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2007'	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:16:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:16:59
Data point term sent to Coder	System	19 Aug 2020 18:15:18
User entered 'hypertension'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2012'	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Chronic post nasal drip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:53:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:53:11
Data point term sent to Coder	System	19 Aug 2020 18:17:21
User entered 'chronic cough due to post nasal drainage'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 1988'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '1988'	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:18:23
Data point term sent to Coder	System	19 Aug 2020 18:17:22
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2014'	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:19:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:19:59
Data point term sent to Coder	System	19 Aug 2020 18:18:26
User entered 'postmenopausal'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '1997'	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Fibrocystic breast disease, LLT: Fibrocystic breast disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:20:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:20:23
Data point term sent to Coder	System	19 Aug 2020 18:19:31
User entered 'fibrocystic breast disease'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2002'	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:22:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:22:32
Data point term sent to Coder	System	19 Aug 2020 18:21:35
User entered 'osteoarthritis left knee'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un Dec 2014'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Dec 2014'	System	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '2014'	System	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '17:53'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 17:53'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '27.10459'	System	16 Sep 2020 23:50:59
User entered '27.1'	System	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 10:51:26
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 19:34:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 04:44:35
User entered '98.2' F	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '69'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '146'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '96'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:09:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:22:50

US3592111

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:09:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:53
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:22:50

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:19

[Specify](#)

Audit	User	Time (GMT)
User entered 'subject goes to church once a week and goes to the grocery stores at least once a week and volunteers at a school with children once a week.'	(b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:27:39
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:27:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:59:09
User entered '185380' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 18:34:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:24:26

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '17:53'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 17:53'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '96'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:31:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:34:00
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:33:19
User entered '19:38'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:38'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:31:25
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:34:26
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Aug 2020 18:33:19
User entered '162'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:31:28
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:34:46
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Aug 2020 18:33:19
User entered '108'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:09:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:35:07

US3592111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:09:24
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:35:07

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '19:07'	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:07'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:30'	(b) (4), (b) (6)	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:30'	System	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	17 Sep 2020 14:15:26
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 14:15:26
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:15:26
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:38:00
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 16:40'	System	17 Sep 2020 14:15:26
User entered empty.	System	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 18:38:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:38:35
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 18:38:35
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:38:00
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:39:18

US3592111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:39:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered 'Yes (Y)'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered '97.5'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered 'No (N)'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered '10 Aug 2020 19:41'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e'	System	11 Aug 2020 22:28:50
User entered 'Yes (Y)'	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e'	System	11 Aug 2020 22:28:50
User entered '98.6'	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e'	System	11 Aug 2020 22:28:50
User entered 'No (N)'	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:49', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e'	System	11 Aug 2020 22:28:50
User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:37:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered 'Yes (Y)'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:37:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered '97.7'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:06', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered 'No (N)'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered '12 Aug 2020 13:38'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d'	System	13 Aug 2020 19:37:06
User entered 'Yes (Y)'	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d'	System	13 Aug 2020 19:37:06
User entered '97.7'	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d'	System	13 Aug 2020 19:37:06
User entered 'No (N)'	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:02', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d'	System	13 Aug 2020 19:37:06
User entered '13 Aug 2020 14:37'	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487'	System	14 Aug 2020 19:07:39
User entered 'Yes (Y)'	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487'	System	14 Aug 2020 19:07:39
User entered '97.9'	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487'	System	14 Aug 2020 19:07:39
User entered 'No (N)'	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487'	System	14 Aug 2020 19:07:39
User entered '14 Aug 2020 14:07'	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:20', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b'	System	15 Aug 2020 17:27:44
User entered 'Yes (Y)'	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b'	System	15 Aug 2020 17:27:44
User entered '98.4'	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b'	System	15 Aug 2020 17:27:44
User entered 'No (N)'	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b'	System	15 Aug 2020 17:27:44
User entered '15 Aug 2020 12:27'	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:43:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered 'Yes (Y)'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered '98.4'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered 'No (N)'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered '16 Aug 2020 14:44'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'None (1)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'No (N)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'No (N)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'None (1)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered '10 Aug 2020 19:42'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'None (1)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'No (N)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'No (N)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'None (1)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered '11 Aug 2020 17:29'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41'	System	12 Aug 2020 18:38:46
User entered 'None (1)'	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41'	System	12 Aug 2020 18:38:46
User entered 'No (N)'	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41'	System	12 Aug 2020 18:38:46
User entered 'No (N)'	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41'	System	12 Aug 2020 18:38:46
User entered 'None (1)'	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:45', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41'	System	12 Aug 2020 18:38:46
User entered '12 Aug 2020 13:38'	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:20', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a'	System	13 Aug 2020 19:37:42
User entered 'None (1)'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a'	System	13 Aug 2020 19:37:42
User entered 'No (N)'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a'	System	13 Aug 2020 19:37:42
User entered 'No (N)'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a'	System	13 Aug 2020 19:37:42
User entered 'None (1)'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a'	System	13 Aug 2020 19:37:42
User entered '13 Aug 2020 14:37'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'None (1)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'No (N)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'No (N)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'None (1)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered '14 Aug 2020 14:08'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'None (1)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'No (N)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'No (N)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'None (1)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered '15 Aug 2020 12:28'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'None (1)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:25', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'No (N)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'No (N)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'None (1)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered '16 Aug 2020 14:44'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'None (0)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'None (0)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'None (0)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'None (0)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'None (0)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered 'No (N)'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f'	System	11 Aug 2020 00:43:31
User entered '10 Aug 2020 19:43'	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'None (0)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered 'No (N)'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:30:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6'	System	11 Aug 2020 22:30:09
User entered '11 Aug 2020 17:30'	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:58', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:02', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'None (0)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered 'No (N)'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9'	System	12 Aug 2020 18:39:25
User entered '12 Aug 2020 13:39'	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:38:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'No (N)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:38:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered '13 Aug 2020 14:38'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'None (0)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered 'No (N)'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3'	System	14 Aug 2020 19:08:46
User entered '14 Aug 2020 14:08'	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'No (N)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered '15 Aug 2020 12:28'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'No (N)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:45:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered '16 Aug 2020 14:45'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:40:46

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:40:46

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 16:12:12

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 16:12:12

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:37:23

US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 16:37:23

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '10:58'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020 10:58'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '133'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	29 Sep 2020 15:26:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 15:26:43
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	08 Sep 2020 18:14:07
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '11:47'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020 11:47'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '85'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:14:14

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:14:14

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '11:16'	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020 11:16'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:05'	(b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020 11:05'	System	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:06'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '7 Sep 2020 11:06'	System	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 15:21:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	29 Sep 2020 15:21:15
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	29 Sep 2020 15:21:15
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:16:25
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:16:29

US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:16:29

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80'	System	07 Sep 2020 16:49:05
User entered 'Yes (Y)'	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80'	System	07 Sep 2020 16:49:05
User entered '97.9'	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80'	System	07 Sep 2020 16:49:05
User entered 'No (N)'	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80'	System	07 Sep 2020 16:49:05
User entered '07 Sep 2020 11:49'	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff'	System	08 Sep 2020 14:05:07
User entered 'Yes (Y)'	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff'	System	08 Sep 2020 14:05:07
User entered '97.9'	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff'	System	08 Sep 2020 14:05:07
User entered 'No (N)'	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff'	System	08 Sep 2020 14:05:07
User entered '08 Sep 2020 09:05'	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:05:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6'	System	09 Sep 2020 14:06:20
User entered 'Yes (Y)'	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6'	System	09 Sep 2020 14:06:20
User entered '97.0'	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6'	System	09 Sep 2020 14:06:20
User entered 'No (N)'	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6'	System	09 Sep 2020 14:06:20
User entered '09 Sep 2020 09:06'	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73'	System	10 Sep 2020 19:49:49
User entered 'Yes (Y)'	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73'	System	10 Sep 2020 19:49:49
User entered '97.5'	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:36', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73'	System	10 Sep 2020 19:49:49
User entered 'No (N)'	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:45', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73'	System	10 Sep 2020 19:49:49
User entered '10 Sep 2020 14:49'	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered 'Yes (Y)'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:11', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered '96.5'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered 'No (N)'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered '11 Sep 2020 13:15'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca'	System	12 Sep 2020 18:58:35
User entered 'Yes (Y)'	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca' User entered '97.7'	System	12 Sep 2020 18:58:35
	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca'	System	12 Sep 2020 18:58:35
User entered 'No (N)'	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca'	System	12 Sep 2020 18:58:35
User entered '12 Sep 2020 13:58'	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered 'Yes (Y)'	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered '98.1'	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered 'No (N)'	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ea4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'None (1)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ea4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'No (N)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ea4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'No (N)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ea4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'None (1)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ea4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered '07 Sep 2020 11:50'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:33', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'No (N)'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'No (N)'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'None (1)'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered '08 Sep 2020 09:06'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a'	System	09 Sep 2020 14:07:00
User entered 'None (1)'	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a'	System	09 Sep 2020 14:07:00
User entered 'No (N)'	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a'	System	09 Sep 2020 14:07:00
User entered 'No (N)'	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a'	System	09 Sep 2020 14:07:00
User entered 'None (1)'	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a'	System	09 Sep 2020 14:07:00
User entered '09 Sep 2020 09:06'	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c'	System	10 Sep 2020 19:50:13
User entered 'None (1)'	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c'	System	10 Sep 2020 19:50:13
User entered 'No (N)'	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:58', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c'	System	10 Sep 2020 19:50:13
User entered 'No (N)'	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c'	System	10 Sep 2020 19:50:13
User entered 'None (1)'	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c'	System	10 Sep 2020 19:50:13
User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'None (1)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'No (N)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'No (N)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'None (1)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered '11 Sep 2020 13:15'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9'	System	12 Sep 2020 18:59:02
User entered 'None (1)'	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9'	System	12 Sep 2020 18:59:02
User entered 'No (N)'	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered 'No (N)'	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9'	System	12 Sep 2020 18:59:02
User entered 'None (1)'	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9'	System	12 Sep 2020 18:59:02
User entered '12 Sep 2020 13:59'	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'None (1)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'No (N)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'No (N)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'None (1)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'None (0)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'None (0)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'None (0)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'None (0)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'None (0)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered 'No (N)'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c'	System	07 Sep 2020 16:50:42
User entered '07 Sep 2020 11:50'	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'None (0)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered 'No (N)'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3'	System	08 Sep 2020 14:06:45
User entered '08 Sep 2020 09:06'	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'None (0)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered 'No (N)'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8'	System	09 Sep 2020 14:07:16
User entered '09 Sep 2020 09:07'	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'None (0)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered 'No (N)'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814'	System	10 Sep 2020 19:50:43
User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'None (0)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:16:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered 'No (N)'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:16:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:11', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'None (0)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered 'No (N)'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9'	System	12 Sep 2020 18:59:28
User entered '12 Sep 2020 13:59'	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:33', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:36', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'None (0)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered 'No (N)'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc'	System	13 Sep 2020 21:31:54
User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:15:13

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 14:15:13

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:44:13

US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:44:13

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:07:10

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:07:10

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '15:28'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 15:28'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 21:07:58

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 21:07:58

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:50'	(b) (4), (b) (6)	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '6 Oct 2020 15:50'	System	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 21:08:10

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 21:08:10

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 64'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:36:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44'	System	10 Oct 2020 12:37:30
User entered 'No (N)'	System	10 Oct 2020 12:37:30

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:37:08', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44'	System	10 Oct 2020 12:37:30
User entered 'No (N)'	System	10 Oct 2020 12:37:30

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:37:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44'	System	10 Oct 2020 12:37:30
User entered '10 Oct 2020 07:37:29'	System	10 Oct 2020 12:37:30

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '10 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '14 Oct 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 71'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613'	System	19 Oct 2020 17:24:27
User entered 'No (N)'	System	19 Oct 2020 17:24:27

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613'	System	19 Oct 2020 17:24:27
User entered 'No (N)'	System	19 Oct 2020 17:24:27

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613' User entered '19 Oct 2020 12:24:26'	System	19 Oct 2020 17:24:27
	System	19 Oct 2020 17:24:27

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '17 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '21 Oct 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 78'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:17:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a'	System	28 Oct 2020 21:18:11
User entered 'No (N)'	System	28 Oct 2020 21:18:11

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:18:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a'	System	28 Oct 2020 21:18:11
User entered 'No (N)'	System	28 Oct 2020 21:18:11

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:18:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a' User entered '28 Oct 2020 16:18:07'	System	28 Oct 2020 21:18:11
	System	28 Oct 2020 21:18:11

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '24 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '28 Oct 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 92'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:07:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'Yes (Y)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:07:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'No (N)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:17:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'No (N)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'Yes (Y)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4' User entered '07 Nov 2020 16:18:41'	System	07 Nov 2020 22:18:49
	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '07 Nov 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '11 Nov 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 99'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:39:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'Yes (Y)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:39:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'No (N)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'No (N)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:08', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'Yes (Y)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d' User entered '14 Nov 2020 18:40:26'	System	15 Nov 2020 00:40:44
	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '14 Nov 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '18 Nov 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered 'Yes (Y)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'No (N)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'No (N)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'Yes (Y)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered '22 Nov 2020 16:43:32'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Oct 2020 15:08:56

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 15:08:56

US3592111

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:16:30
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 14:18:16

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:30
User entered 'USA-US103-2020-mRNA-1273-P301000005'	System	10 Nov 2020 17:22:23
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 17:22:23

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastrointestinal ulcers and perforation, site unspecified, PT: Diverticular perforation, LLT: Diverticular perforation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:50:27
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 05:50:27
Data point term sent to Coder	System	09 Nov 2020 20:19:33
User entered 'perforated diverticulitis'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '03 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:13:12
	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 06:21:46
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 'confirm correct subject has not be discharged. ' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 20:20:39
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	09 Nov 2020 20:19:22
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '05 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:12:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 20:37:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 20:37:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:37:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 20:19:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:13:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:13:28
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)	19 Nov 2020 20:12:59
User opened query 'PV query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:12:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:37:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 20:37:14

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CRC was notified of subjects hospitalization upon receive message from the weekend. TC to subject made at 0805 and 0840 to obtain more information. Subject is currently hospitalized at St Francis hospital. per subject report she was experiencing abdominal pain on 03NOV2020 and presented to ER at approximately 0330. During that visit a CT scan was performed and subject was told she had diverticulitis with perforation. She was given Morphine and dilaudid for pain control in the ER. Subject stated that they sent her home from ER about 2 hours later with Augmentin and hydrocodone and instructions to follow up with PCP. Subject was not able to get into her PCPS office for a follow appt until afternoon on Thursday 05nov2020. During that visit subject pcp felt it necessary to directly admit subject to the hospital for further assessments and treatment. REPEAT ct SCAN DONE upon admission also identified an abscess in the bowel. Subject continues to be admitted to hospital she is on a clear liquid diet and receiving medication for pain management and nausea control. Per subject the current plan is to monitor for improvements/decline while she receives IV antibiotics and IV fluids,. No surgery has been done and there are no plans for surgery at this time. Will obtain medical records for more precise information. Additional during TC subject confirmed that she has no known history of diverticulitis or any other GI condition prior to this.' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:37:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:19:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Colonic abscess, LLT: Colonic abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:52:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:52:43
Data point term sent to Coder	System	09 Nov 2020 20:39:07
User entered 'colon abscess'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '05 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 20:38:38

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:42:46

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:45:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:45:24
Data point term sent to Coder	System	19 Aug 2020 18:44:33
User entered 'telmisartan'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:22:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:44:11
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:43:57
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:47:48
Data point term sent to Coder	System	19 Aug 2020 18:46:36
User entered 'levothyroxine'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:22:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:46:33
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:45:56
User entered 'un UNK 2014'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:33:27
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' answered with 'corrected to yes' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:05:06
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	07 Oct 2020 21:04:57
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:49:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:49:23
Data point term sent to Coder	System	19 Aug 2020 18:48:42
User entered 'liothyronine'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '7.5'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:23:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:48:46
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:48:34
User entered '1 May 2020'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:51:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:51:29
Data point term sent to Coder	System	19 Aug 2020 18:50:47
User entered 'multivitamin'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:24:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:50:34
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:50:24
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:53:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:53:19
Data point term sent to Coder	System	19 Aug 2020 18:52:51
User entered 'calcium'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:52:22
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:52:01
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:58:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 20:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:56:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 18:56:24
Data point term sent to Coder	System	19 Aug 2020 18:54:56
User entered 'vitamin d'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:54:26
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:54:15
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 01:34:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 01:34:45
Data point term sent to Coder	System	19 Aug 2020 18:55:58
User entered 'phenylephrine'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'chronic cough'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:55:56
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:55:44
User entered 'un UNK 2011'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:24:43
Data point term sent to Coder	System	30 Sep 2020 21:22:56
User entered 'fexofenadine'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:27:45
User entered 'chronic cough'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered 'un UNK 2011'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 21:24:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 21:24:47
Data point term sent to Coder	System	30 Sep 2020 21:23:57
User entered 'influenza vaccine'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 14:18:32

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'USA-US103-2020-MRNA-1273-P301000005'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
User entered 'US'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'USA-US103-2020-MRNA-1273-P301000005'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
User entered 'US'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:38:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
User entered '10/Nov/2020 17:23'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:38:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:21
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 17:23:05