

US3822006 (Prod: Tryon Medical Partners, PLLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:21:55

All time stamps listed in this document are displayed in GMT

US3822006

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:55

[Participant ID](#)

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

US3822006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 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 11:21:55

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
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 11:21:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 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 11:21:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

Condition	EXERCISE INDUCED ASTHMA
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

Condition	PSORIASIS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

Condition	COLD SORES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:56 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:56
Height (<i>xxx.x</i>)	66.3 in
Weight (<i>xxx.x</i>)	121.6 lb
BMI (<i>xxx.x</i>)	19.49020 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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 11:21:55

Date of assessment (*dd MMM yyyy*) 04 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 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)	False
Other	True
Specify	CHILDREN IN THE HOME WHO WILL BE GOING TO COLLEGE ON CAMPUS THIS YEAR

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 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 11:21:55

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100849

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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)	04 AUG 2020
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:56
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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)	04 AUG 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:20
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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)	04 AUG 2020
What was the treatment time? (00:00-23:59)	15:51 (24 HR)
Treatment Date and Time (derived)	04 AUG 2020 15:51
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	04 AUG 2020
Collection time (<i>00:00-23:59</i>)	15:11 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:55

Collection date (<i>dd MMM yyyy</i>)			04 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	15:20	04 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

04 AUG 2020 16:12

PC Open Date & Time

04 AUG 2020 16:11

PC Close Date & Time

04 AUG 2020 18:41

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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

97.5 °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

05 AUG 2020 08:05

PC Open Date & Time

04 AUG 2020 19:36

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

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

97.1 °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

06 AUG 2020 06:33

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

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

97.5 °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

07 AUG 2020 06:48

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:55

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**

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 07 AUG 2020 12:00

PC Close Date & Time 08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 14:28

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

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.

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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

09 AUG 2020 13:14

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 21:52

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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

04 AUG 2020 16:13

PC Open Date & Time

04 AUG 2020 16:11

PC Close Date & Time

04 AUG 2020 18:41

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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

05 AUG 2020 08:06

PC Open Date & Time

04 AUG 2020 19:36

PC Close Date & Time

05 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

DAY 2

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

06 AUG 2020 06:34

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

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

07 AUG 2020 06:48

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:55

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 ☐

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

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

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

08 AUG 2020 14:28

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

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

09 AUG 2020 13:14

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

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

10 AUG 2020 21:52

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:13
PC Open Date & Time	04 AUG 2020 16:11
PC Close Date & Time	04 AUG 2020 18:41

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 08:06
PC Open Date & Time	04 AUG 2020 19:36
PC Close Date & Time	05 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

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 ☒

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

Yes ☐	
PC Time stamp	06 AUG 2020 06:34
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

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 ☒

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

Yes ☐	
PC Time stamp	07 AUG 2020 06:49
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

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 ☒

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

Yes ☐	
PC Time stamp	08 AUG 2020 14:29
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

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 ☒

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

Yes ☐	
PC Time stamp	09 AUG 2020 13:14
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

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 ☒

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

Yes ☐	
PC Time stamp	10 AUG 2020 21:52
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Was Contact Attempted?

Yes ☒

No ☐

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

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Was Contact Attempted?

Yes ☒

No ☐

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

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Was Contact Attempted?

Yes ☒

No ☐

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

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:08
Temperature (xxx.x)	98.2 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)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

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.

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	8 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:21 (24 HR)
Collection date and time (derived)	8 SEP 2020 16:21

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:55

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:40	8 SEP 2020 16:40
Nasopharyngeal Swab 2	No		

US3822006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:44 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 07:44
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

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.

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	2 OCT 2020
Collection time (<i>00:00-23:59</i>)	07:48 (24 HR)
Collection date and time (derived)	2 OCT 2020 07:48

US3822006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

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

Date and time of submission

03 NOV 2020 11:34:05

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

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

Date and time of submission

10 NOV 2020 12:07:07

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 12:00:23

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 07:57:10
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUN 2021 00:01

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21 JUN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUN 2021 00:01

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28 JUN 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUL 2021 00:01

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12 JUL 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 AUG 2021 00:01

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09 AUG 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 AUG 2021 00:01

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23 AUG 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 AUG 2021 00:01

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30 AUG 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

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27 DEC 2021 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2021 00:01

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03 JAN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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10 JAN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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20 JAN 2022 00:01

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24 JAN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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31 JAN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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07 FEB 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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21 FEB 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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28 FEB 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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07 MAR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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14 MAR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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17 MAR 2022 00:01

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21 MAR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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28 MAR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 MAR 2022 00:01

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04 APR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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07 APR 2022 00:01

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11 APR 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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02 MAY 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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09 MAY 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 MAY 2022 00:01

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16 MAY 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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30 MAY 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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06 JUN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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13 JUN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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04 JUL 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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28 JUL 2022 00:01

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01 AUG 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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

Date and time of submission

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11 AUG 2022 00:01

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15 AUG 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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18 AUG 2022 00:01

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22 AUG 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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05 SEP 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

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12 SEP 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822006

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:21:55

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 ☐

US3822006

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:21:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

AEID

Adverse event

SWELLING UNDER EYE,
BILATERAL

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

9 AUG 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

v6.020 DTW (1102)

304 of 1393

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

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	PATIENT HAD RECEIVED JUVEDERM 3 MONTHS PRIOR TO TRIAL INITIATION. SWELLING EVENTUALLY RESOLVED AFTER STEROIDS AND HYALURONIC ACID
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)	

v6.020 DTW (1102)

305 of 1393

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:55

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

Yes ☒

No ☐

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

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	CLOBETASOL 0.05%
Prophylaxis	Yes ☐ No ☒
Indication	PSORIASIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	VALTREX
Prophylaxis	Yes ☐ No ☒
Indication	COLD SORES
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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

	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 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

	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 2000	
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 ☒	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	ALBUTEROL MDI
Prophylaxis	Yes ☐ No ☒
Indication	EXERCISE INDUCED ASTHMA
Dose per administration	90
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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

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

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	TD
Prophylaxis	Yes ☒
	No ☐
Indication	VACCINE
Dose per administration	UNK
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 ☒

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

	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 JAN 2010
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2010
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	☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	INFLUENZA
Prophylaxis	Yes ☒ No ☐
Indication	VACCINE
Dose per administration	UNK
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 ☒

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

	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 SEP 2019
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
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	☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	INFLAMMATION UNDER EYES BILATERALLY
Dose per administration	24-5
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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 AUG 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	☒

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

Name of Medication JUVEDERM VOLUMA FILLER
UNDER BILATERAL EYES.

Prophylaxis Yes ☒
No ☐

Indication COSMETIC ENHANCEMENT

Dose per administration UNK

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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN JUN 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	☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

Name of Medication	DOXCYCLINE
Prophylaxis	Yes ☐ No ☒
Indication	SWELLING UNDER LEFT EYE
Dose per administration	100
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 ☐

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

	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)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		17 AUG 2020
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 ☒	

US3822006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:55

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:55

Date of dosing discontinuation (dd MMM yyyy)

8 SEP 2020

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

SWELLING UNDER LEFT EYE,
AE #1

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:21:55

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 ☐

Audit

US3822006 (Prod: Tryon Medical Partners, PLLC)

US3822006

Form: Participant Creation

Generated On: 26 Nov 2020 11:21:55

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3822006'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:24:36

US3822006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:24:37

US3822006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:24:38

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Age](#)

Audit	User	Time (GMT)
User entered '51'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

White

Audit	User	Time (GMT)
User entered '1'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

Unknown

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:21:55

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 19:34:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 19:34:16
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	04 Aug 2020 19:34:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 19:34:11
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:24:37

US3822006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:21:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:21:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:35:48

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:00:50
Query 'Per DM CLR: Please note that there is no Con Krishna Shah Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated ' (Site from DM).	(b) (4)	28 Sep 2020 15:54:44
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:21:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 14:38:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 14:38:19
Data point term sent to Coder	System	06 Aug 2020 14:36:51
User entered 'Exercise induced asthma'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2020'	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:38:20
Data point term sent to Coder	System	06 Aug 2020 14:36:51
User entered 'Psoriasis'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40
	(b) (4)	

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '1985'	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Cold sores - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 14:39:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 14:39:21
Data point term sent to Coder	System	06 Aug 2020 14:37:52
User entered 'Cold sores'	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

[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)	08 Oct 2020 20:48:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Oct 2020 20:48:25
Data point term sent to Coder	System	08 Oct 2020 14:17:36
User entered 'Post menopausal'	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09
	(b) (4)	

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2005'	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '14:56'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 14:56'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '121.6' lb	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02
DataPoint set to visible.	(b) (4) System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '19.49020'	System	16 Sep 2020 23:43:02
User entered '19.5'	System	06 Aug 2020 14:38:02
DataPoint set to visible.	System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Aug 2020 14:38:02
DataPoint set to visible.	System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:01
User entered '98.0' F	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:01
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:01
User entered '64'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:01
User entered '14'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:01
User entered '118'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:01
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:53:35
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Kelly Woodell (b) (4)	16 Sep 2020 23:45:35
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:43:02
User entered '56'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:57

US3822006

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:38:57

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:05:36
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'added' (Site from DM).	Kelly Woodell (b) (4)	08 Oct 2020 14:16:44
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:37:25
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:21:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

[Other](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 01:19:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 01:19:30
User entered 'No (N)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	26 Aug 2020 01:19:30
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:40:22
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

No Risk Identified

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4)	06 Aug 2020 14:41:40
User entered '1'	(b) (4) Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Kelly Woodell (b) (4)	06 Aug 2020 14:41:40
User entered '0'	(b) (4) Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:21:55

[Specify](#)

Audit	User	Time (GMT)
User entered 'Children in the home who will be going to college on campus this year' reason for change: Data Entry Error	Kelly Woodell (b) (4)	06 Aug 2020 14:41:40
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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 02:04:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:04:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:34:29
User entered '100849' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:21:55

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:19
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:19
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '14:56'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 14:56'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '64'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '14'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 09:19:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Kelly Woodell (b) (4)	16 Sep 2020 23:46:13
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:43:02
User entered '56'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:02:19
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:21:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User closed query 'Per CDM: The treatment time on the Exposure CRF is 15:51. The Vital Signs Post Dose Time of Assessment is 16:20 (which is 29 minutes after dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 16:59:23
Query 'Per CDM: The treatment time on the Exposure CRF is 15:51. The Vital Signs Post Dose Time of Assessment is 16:20 (which is 29 minutes after dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'Time is correct as is. Site inadvertently did not wait 30 minutes to collect vitals.' (Site from DM).	Kelly Woodell (b) (4)	26 Aug 2020 01:21:06
User opened query 'Per CDM: The treatment time on the Exposure CRF is 15:51. The Vital Signs Post Dose Time of Assessment is 16:20 (which is 29 minutes after dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	14 Aug 2020 14:05:20
Query 'Per CDM: The treatment time on the Exposure CRF is 15:51. The Vital Signs Post Dose Time of Assessment is 16:20 (which is 29 minutes after dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' canceled (Site from DM).	(b) (4), (b) (6)	12 Aug 2020 08:27:06
User opened query 'Per CDM: The treatment time on the Exposure CRF is 15:51. The Vital Signs Post Dose Time of Assessment is 16:20 (which is 29 minutes after dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	10 Aug 2020 10:09:39
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)	10 Aug 2020 10:08:43

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User		Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals collected 30 min post dose per protocol' (Site from System).	Kelly Woodell (b) (4)	(b) (4)	06 Aug 2020 14:44:02
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).			06 Aug 2020 14:43:37
User entered '16:20'	Kelly Woodell (b) (4)	(b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:20'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '60'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '18'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:10

US3822006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '15:51'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:51'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4) (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:11'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:11'	System	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:20'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:20'	System	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User closed query 'Per CDM: 'Is the participant continuing to the next visit?' is Yes, hence please complete all the applicable pages for the next visit 2. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:25:05
Query 'Per CDM: 'Is the participant continuing to the next visit?' is Yes, hence please complete all the applicable pages for the next visit 2. Else Clarify. ' answered with 'updated. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:24:46
User opened query 'Per CDM: 'Is the participant continuing to the next visit?' is Yes, hence please complete all the applicable pages for the next visit 2. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 06:33:46
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	06 Aug 2020 14:44:51

US3822006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:44:51

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:26', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '94709a54-015a-4d37-b9b4-a3bf5227e56d'	System	04 Aug 2020 20:12:42
User entered 'Yes (Y)'	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:32', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '94709a54-015a-4d37-b9b4-a3bf5227e56d'	System	04 Aug 2020 20:12:42
User entered '98.9'	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:36', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '94709a54-015a-4d37-b9b4-a3bf5227e56d'	System	04 Aug 2020 20:12:42
User entered 'No (N)'	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:40', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '94709a54-015a-4d37-b9b4-a3bf5227e56d'	System	04 Aug 2020 20:12:42
User entered '04 Aug 2020 16:12'	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:41'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:04:36', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ac451a63-d9da-4785-89f7-0e2cd47f5567'	System	05 Aug 2020 12:05:55
User entered 'Yes (Y)'	System	05 Aug 2020 12:05:55

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:05:47', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ac451a63-d9da-4785-89f7-0e2cd47f5567'	System	05 Aug 2020 12:05:55
User entered '97.5'	System	05 Aug 2020 12:05:55

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:05:49', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ac451a63-d9da-4785-89f7-0e2cd47f5567'	System	05 Aug 2020 12:05:55
User entered 'No (N)'	System	05 Aug 2020 12:05:55

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:05:53', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ac451a63-d9da-4785-89f7-0e2cd47f5567'	System	05 Aug 2020 12:05:55
User entered '05 Aug 2020 08:05'	System	05 Aug 2020 12:05:55

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:36'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 2'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:13', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '7d0ed823-6047-4bd5-9100-b3c3f964cbb4'	System	06 Aug 2020 10:33:25
User entered 'Yes (Y)'	System	06 Aug 2020 10:33:25

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:17', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '7d0ed823-6047-4bd5-9100-b3c3f964cbb4'	System	06 Aug 2020 10:33:25
User entered '97.1'	System	06 Aug 2020 10:33:25

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:19', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '7d0ed823-6047-4bd5-9100-b3c3f964cbb4'	System	06 Aug 2020 10:33:25
User entered 'No (N)'	System	06 Aug 2020 10:33:25

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:23', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '7d0ed823-6047-4bd5-9100-b3c3f964cbb4' User entered '06 Aug 2020 06:33'	System	06 Aug 2020 10:33:25
	System	06 Aug 2020 10:33:25

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 3'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:02', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '0d810ef5-4133-4628-b436-cf7846cbced8'	System	07 Aug 2020 10:48:15
User entered 'Yes (Y)'	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:07', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '0d810ef5-4133-4628-b436-cf7846cbced8'	System	07 Aug 2020 10:48:15
User entered '97.5'	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:09', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '0d810ef5-4133-4628-b436-cf7846cbced8'	System	07 Aug 2020 10:48:15
User entered 'No (N)'	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:12', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '0d810ef5-4133-4628-b436-cf7846cbced8'	System	07 Aug 2020 10:48:15
User entered '07 Aug 2020 06:48'	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 4'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 5'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:11', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e67e306f-f506-41a5-860e-14bafb8a0369'	System	08 Aug 2020 18:28:20
User entered 'Yes (Y)'	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:15', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e67e306f-f506-41a5-860e-14bafb8a0369'	System	08 Aug 2020 18:28:20
User entered '98.2'	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:17', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e67e306f-f506-41a5-860e-14bafb8a0369'	System	08 Aug 2020 18:28:20
User entered 'No (N)'	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:18', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e67e306f-f506-41a5-860e-14bafb8a0369'	System	08 Aug 2020 18:28:20
User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 6'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:13:56', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1bf88ebd-6739-4ae0-92e9-3ba44757e732'	System	09 Aug 2020 17:14:08
User entered 'Yes (Y)'	System	09 Aug 2020 17:14:08

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:01', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1bf88ebd-6739-4ae0-92e9-3ba44757e732'	System	09 Aug 2020 17:14:08
User entered '98.6'	System	09 Aug 2020 17:14:08

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:03', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1bf88ebd-6739-4ae0-92e9-3ba44757e732'	System	09 Aug 2020 17:14:08
User entered 'No (N)'	System	09 Aug 2020 17:14:08

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:05', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1bf88ebd-6739-4ae0-92e9-3ba44757e732'	System	09 Aug 2020 17:14:08
User entered '09 Aug 2020 13:14'	System	09 Aug 2020 17:14:08

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 7'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:01', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e60ec075-b5c8-4ddf-8691-55adce7b52aa'	System	11 Aug 2020 01:52:13
User entered 'Yes (Y)'	System	11 Aug 2020 01:52:13

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:06', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e60ec075-b5c8-4ddf-8691-55adce7b52aa'	System	11 Aug 2020 01:52:13
User entered '97.8'	System	11 Aug 2020 01:52:13

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:09', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e60ec075-b5c8-4ddf-8691-55adce7b52aa'	System	11 Aug 2020 01:52:13
User entered 'No (N)'	System	11 Aug 2020 01:52:13

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:11', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e60ec075-b5c8-4ddf-8691-55adce7b52aa'	System	11 Aug 2020 01:52:13
User entered '10 Aug 2020 21:52'	System	11 Aug 2020 01:52:13

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:50', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'b01541e1-9a0a-4e34-aaf3-c76b52da95e6'	System	04 Aug 2020 20:13:16
User entered 'None (1)'	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:56', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'b01541e1-9a0a-4e34-aaf3-c76b52da95e6'	System	04 Aug 2020 20:13:16
User entered 'No (N)'	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:12:59', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'b01541e1-9a0a-4e34-aaf3-c76b52da95e6'	System	04 Aug 2020 20:13:16
User entered 'No (N)'	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:11', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'b01541e1-9a0a-4e34-aaf3-c76b52da95e6'	System	04 Aug 2020 20:13:16
User entered 'None (1)'	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:14', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'b01541e1-9a0a-4e34-aaf3-c76b52da95e6'	System	04 Aug 2020 20:13:16
User entered '04 Aug 2020 16:13'	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:41'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:05:59', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c7deac6a-a08f-41d4-a5d1-ac34e430eaac'	System	05 Aug 2020 12:06:21
User entered 'None (1)'	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:02', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c7deac6a-a08f-41d4-a5d1-ac34e430eaac'	System	05 Aug 2020 12:06:21
User entered 'No (N)'	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:08', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c7deac6a-a08f-41d4-a5d1-ac34e430eaac'	System	05 Aug 2020 12:06:21
User entered 'No (N)'	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:16', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c7deac6a-a08f-41d4-a5d1-ac34e430eaac'	System	05 Aug 2020 12:06:21
User entered 'None (1)'	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:20', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c7deac6a-a08f-41d4-a5d1-ac34e430eaac'	System	05 Aug 2020 12:06:21
User entered '05 Aug 2020 08:06'	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:36'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 2'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:49', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '028c56e2-ba98-4d3b-ba34-2a61602700ae'	System	06 Aug 2020 10:34:17
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 10:34:17

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:33:52', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '028c56e2-ba98-4d3b-ba34-2a61602700ae'	System	06 Aug 2020 10:34:17
User entered 'No (N)'	System	06 Aug 2020 10:34:17

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:03', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '028c56e2-ba98-4d3b-ba34-2a61602700ae'	System	06 Aug 2020 10:34:17
User entered 'No (N)'	System	06 Aug 2020 10:34:17

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:12', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '028c56e2-ba98-4d3b-ba34-2a61602700ae'	System	06 Aug 2020 10:34:17
User entered 'None (1)'	System	06 Aug 2020 10:34:17

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:15', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '028c56e2-ba98-4d3b-ba34-2a61602700ae' User entered '06 Aug 2020 06:34'	System	06 Aug 2020 10:34:17
	System	06 Aug 2020 10:34:17

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 3'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:16', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '3297f333-a7bb-4d06-a397-72d256c1bbaa'	System	07 Aug 2020 10:48:49
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:19', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '3297f333-a7bb-4d06-a397-72d256c1bbaa'	System	07 Aug 2020 10:48:49
User entered 'No (N)'	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:43', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '3297f333-a7bb-4d06-a397-72d256c1bbaa'	System	07 Aug 2020 10:48:49
User entered 'No (N)'	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:46', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '3297f333-a7bb-4d06-a397-72d256c1bbaa'	System	07 Aug 2020 10:48:49
User entered 'None (1)'	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:48', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '3297f333-a7bb-4d06-a397-72d256c1bbaa'	System	07 Aug 2020 10:48:49
User entered '07 Aug 2020 06:48'	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 4'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 5'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:23', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f583ee74-9531-402d-8a5a-c11eada875d9'	System	08 Aug 2020 18:28:47
User entered 'None (1)'	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:29', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f583ee74-9531-402d-8a5a-c11eada875d9'	System	08 Aug 2020 18:28:47
User entered 'No (N)'	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:31', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f583ee74-9531-402d-8a5a-c11eada875d9'	System	08 Aug 2020 18:28:47
User entered 'No (N)'	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:42', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f583ee74-9531-402d-8a5a-c11eada875d9'	System	08 Aug 2020 18:28:47
User entered 'None (1)'	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:44', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f583ee74-9531-402d-8a5a-c11eada875d9'	System	08 Aug 2020 18:28:47
User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 6'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:19', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c65d0ee6-aaf2-4b4e-b936-469411dfefab'	System	09 Aug 2020 17:14:36
User entered 'None (1)'	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:22', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c65d0ee6-aaf2-4b4e-b936-469411dfefab'	System	09 Aug 2020 17:14:36
User entered 'No (N)'	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:25', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c65d0ee6-aaf2-4b4e-b936-469411dfefab'	System	09 Aug 2020 17:14:36
User entered 'No (N)'	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:33', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c65d0ee6-aaf2-4b4e-b936-469411dfefab'	System	09 Aug 2020 17:14:36
User entered 'None (1)'	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:35', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'c65d0ee6-aaf2-4b4e-b936-469411dfefab'	System	09 Aug 2020 17:14:36
User entered '09 Aug 2020 13:14'	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 7'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:15', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ae91bf39-9763-40fc-9489-950b7e52e458'	System	11 Aug 2020 01:52:27
User entered 'None (1)'	System	11 Aug 2020 01:52:27

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:18', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ae91bf39-9763-40fc-9489-950b7e52e458'	System	11 Aug 2020 01:52:27
User entered 'No (N)'	System	11 Aug 2020 01:52:27

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:20', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ae91bf39-9763-40fc-9489-950b7e52e458'	System	11 Aug 2020 01:52:27
User entered 'No (N)'	System	11 Aug 2020 01:52:27

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:22', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ae91bf39-9763-40fc-9489-950b7e52e458'	System	11 Aug 2020 01:52:27
User entered 'None (1)'	System	11 Aug 2020 01:52:27

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:24', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'ae91bf39-9763-40fc-9489-950b7e52e458'	System	11 Aug 2020 01:52:27
User entered '10 Aug 2020 21:52'	System	11 Aug 2020 01:52:27

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:19', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:22', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:25', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:30', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:32', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:34', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'None (0)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:39', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered 'No (N)'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-04T16:13:41', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'f56ec379-ccab-4f53-a9a3-eb918ea3bd28'	System	04 Aug 2020 20:13:43
User entered '04 Aug 2020 16:13'	System	04 Aug 2020 20:13:43

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:41'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:26', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:27', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:29', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:32', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:34', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:35', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'None (0)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:38', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered 'No (N)'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-05T08:06:40', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'a454324c-b73b-4ad7-b1da-fec29ab3d320'	System	05 Aug 2020 12:06:42
User entered '05 Aug 2020 08:06'	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:36'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 2'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:21', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:25', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:28', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:30', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:32', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:34', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'None (0)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:37', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered 'No (N)'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-06T06:34:41', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '23b60d9a-f0fd-499e-b4b2-3d870a5cb329'	System	06 Aug 2020 10:34:42
User entered '06 Aug 2020 06:34'	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 3'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:52', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:54', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:56', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:48:58', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:49:00', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:49:02', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'None (0)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:49:04', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de'	System	07 Aug 2020 10:49:11
User entered 'No (N)'	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-07T06:49:06', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1dafc3bb-88c1-4399-9a6f-addab6a700de' User entered '07 Aug 2020 06:49'	System	07 Aug 2020 10:49:11
	System	07 Aug 2020 10:49:11

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 4'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 5'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:47', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:49', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:50', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:52', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:53', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:55', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'None (0)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:28:59', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered 'No (N)'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-08T14:29:01', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '2e93a066-00c0-4c29-a13a-70fffb399eb4'	System	08 Aug 2020 18:29:03
User entered '08 Aug 2020 14:29'	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 6'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:41', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:42', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:44', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:45', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:47', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:48', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'None (0)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:50', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered 'No (N)'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-09T13:14:52', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '80d9ac05-579e-4eb6-b1de-d05fc555c2e4'	System	09 Aug 2020 17:14:54
User entered '09 Aug 2020 13:14'	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 7'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:29', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:31', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:32', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:33', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:35', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:37', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'None (0)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:39', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered 'No (N)'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-08-10T21:52:41', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '64affbf4-6400-4274-9e1f-47954fa23bb6'	System	11 Aug 2020 01:52:44
User entered '10 Aug 2020 21:52'	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:21:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:16

US3822006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 15:15:16

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Sep 2020 15:15:48
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	07 Sep 2020 15:15:48
User entered '19 Aug 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	07 Sep 2020 15:15:48
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Sep 2020 15:15:29
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:15:52

US3822006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 15:15:52

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 15:16:09

US3822006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 15:16:09

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '16:08'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:08'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '18'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:21:02
Query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' answered with 'Vitals were not collected post dose as subject did not receive 2nd dose of IP' (Site from DM).	Kelly Woodell (b) (4)	07 Oct 2020 23:56:28
User opened query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:23:00
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:27

US3822006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:27

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Was study treatment given? as No. Hence please complete the 'Dosing discontinuation' page.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:21:58
Query 'Per CDM: Was study treatment given? as No. Hence please complete the 'Dosing discontinuation' page.' answered with 'Completed' (Site from DM).	Kelly Woodell (b) (4)	15 Oct 2020 23:57:03
User opened query 'Per CDM: Was study treatment given? as No. Hence please complete the 'Dosing discontinuation' page.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:36:01
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		28 Sep 2020 15:59:36
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 15:59:36
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	28 Sep 2020 15:57:40
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:21'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:21'	System	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:21:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:40'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:40'	System	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:11

US3822006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:01:11

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:05

US3822006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:02:05

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:31

US3822006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:02:31

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 22:15:48

US3822006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 22:15:48

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:21:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '07:44'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 07:44'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '91'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:21:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 22:17:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:21:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 22:17:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:48'	(b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 07:48'	System	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 22:17:34

US3822006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 22:17:34

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 92'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-03T11:33:58', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e4f4bd00-dfea-4dad-9c06-e087b71ad9e1'	System	03 Nov 2020 16:34:08
User entered 'No (N)'	System	03 Nov 2020 16:34:08

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Have you been exposed to someone with 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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-03T11:34:01', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e4f4bd00-dfea-4dad-9c06-e087b71ad9e1'	System	03 Nov 2020 16:34:08
User entered 'No (N)'	System	03 Nov 2020 16:34:08

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-03T11:34:05', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'e4f4bd00-dfea-4dad-9c06-e087b71ad9e1'	System	03 Nov 2020 16:34:08
User entered '03 Nov 2020 11:34:05'	System	03 Nov 2020 16:34:08

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 99'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-10T12:06:58', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1556f524-c679-4575-86a8-3d20c7c90e06'	System	10 Nov 2020 17:07:15
User entered 'No (N)'	System	10 Nov 2020 17:07:15

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Have you been exposed to someone with 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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-10T12:07:04', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1556f524-c679-4575-86a8-3d20c7c90e06'	System	10 Nov 2020 17:07:15
User entered 'No (N)'	System	10 Nov 2020 17:07:15

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-10T12:07:07', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '1556f524-c679-4575-86a8-3d20c7c90e06' User entered '10 Nov 2020 12:07:07'	System	10 Nov 2020 17:07:15
	System	10 Nov 2020 17:07:15

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 106'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-17T12:00:18', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '6cce4397-dbbb-44f2-9f43-19b219bd4678'	System	17 Nov 2020 17:00:42
User entered 'No (N)'	System	17 Nov 2020 17:00:42

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

Have you been exposed to someone with 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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-17T12:00:21', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '6cce4397-dbbb-44f2-9f43-19b219bd4678'	System	17 Nov 2020 17:00:42
User entered 'No (N)'	System	17 Nov 2020 17:00:42

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-17T12:00:23', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '6cce4397-dbbb-44f2-9f43-19b219bd4678' User entered '17 Nov 2020 12:00:23'	System	17 Nov 2020 17:00:42
	System	17 Nov 2020 17:00:42

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-22T07:57:06', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'aa793364-e8bc-43c8-89c1-8acdc1ed3ed9' User entered 'No (N)'	System	22 Nov 2020 12:57:15
	System	22 Nov 2020 12:57:15

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Have you been exposed to someone with 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 (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-22T07:57:08', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'aa793364-e8bc-43c8-89c1-8acdc1ed3ed9'	System	22 Nov 2020 12:57:15
User entered 'No (N)'	System	22 Nov 2020 12:57:15

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-22T07:57:10', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: 'aa793364-e8bc-43c8-89c1-8acdc1ed3ed9' User entered '22 Nov 2020 07:57:10'	System	22 Nov 2020 12:57:15
	System	22 Nov 2020 12:57:15

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:50:50

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:21:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:50
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:21:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:41

US3822006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:21:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 17:03:41

US3822006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:21:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:03:09

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Kindly confirm if this is bilateral eye swelling.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:08:48
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Eye swelling, LLT: Eye swelling - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 13:04:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	10 Nov 2020 13:04:30
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:14:35
Data point term sent to Coder	System	06 Nov 2020 21:17:06
Query 'Kindly confirm if this is bilateral eye swelling.' answered with 'Per patient started with left eye then progressed to right eye. (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 21:16:24
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, provide comment.' answered with 'Per patient she had juvederm filler placed under eyes which reacted to the vaccine. Patient has no underlying medical condition. (Site from DM).	Krishna Shah (b) (4)	06 Nov 2020 21:16:14
Coding entries removed.	Krishna Shah (b) (4)	06 Nov 2020 21:16:08
User entered 'SWELLING UNDER eye, bilateral' reason for change: Data Entry Error	Krishna Shah (b) (4)	06 Nov 2020 21:16:08
User opened query 'Kindly confirm if this is bilateral eye swelling.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:48:33
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Eye swelling, LLT: Eye swelling - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 18:23:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	04 Nov 2020 18:23:27
Data point term sent to Coder	System	04 Nov 2020 18:22:47
Coding entries removed.	Christina Kennelly (b) (4)	04 Nov 2020 18:22:08

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'SWELLING UNDER LEFT EYE'	Christina Kennelly (b) (4)	04 Nov 2020 18:22:08
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, please update to record the underlying medical condition/diagnosis as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:26:34
User coded data point as SOC: Eye disorders, HLGT: Ocular infections, irritations and inflammations, HLT: Lid, lash and lacrimal infections, irritations and inflammations, PT: Swelling of eyelid, LLT: Swelling of eyelid - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:57:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	08 Oct 2020 10:57:02
Data point term sent to Coder	System	28 Sep 2020 16:04:58
User entered 'Sweling under left eye'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41
	(b) (4)	

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Aug 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Sep 2020 16:04:57
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 16:04:57
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Sep 2020 16:04:41
User entered '08:00'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:04:57
User entered '9 Aug 2020 08:00'	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

None

Audit	User	Time (GMT)
Query 'Per CDM: Other action take= none, however, per Narrative and ConMed eCRF, PREDNISONE (#7) and DOXYCYCLINE (#9) were both recorded as taken for inflammation under eyes during AE timeframe. Please update to Concomitant medication=yes. Otherwise, clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:39:34
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:39:26
User opened query 'Per CDM: Other action take= none, however, per Narrative and ConMed eCRF, PREDNISONE (#7) and DOXYCYCLINE (#9) were both recorded as taken for inflammation under eyes during AE timeframe. Please update to Concomitant medication=yes. Otherwise, clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 16:14:39
User entered '1'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 17:39:26
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:05:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:05:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 16:05:04
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:04:41
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per Narrative, swelling resolved after steroids and Hyaluronic Acid. Please confirm if patient has recovered. If so, please update OUTCOME to Recovered and ONGOING to No and enter an end date. Thank you.' answered with 'Per the patient it has not completely resolved. It will get better but has not completed resolved.' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	24 Nov 2020 21:06:51
User opened query 'Per CDM: Per Narrative, swelling resolved after steroids and Hyaluronic Acid. Please confirm if patient has recovered. If so, please update OUTCOME to Recovered and ONGOING to No and enter an end date. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	22 Nov 2020 16:17:06
User entered 'Patient had received Juvederm 3 months prior to trial initiation. Swelling eventually resolved after steroids and hyaluronic acid' reason for change: Data Entry Error	Christina Kennelly (b) (4) (b) (4)	04 Nov 2020 18:21:56
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:21:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:04:41

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:21:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:09:29
User closed query 'Per source it is noted that subject received doxycycline x4 days. Kindly ensure con meds used for AE are updated in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:09:27
User closed query 'Per source subject received juvaderm, kindly update con meds data in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:09:16
Query 'Per source subject received juvaderm, kindly update con meds data in EDC. Thank you.' answered with 'updated both conmeds ' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 21:12:48
Query 'Per source it is noted that subject received doxycycline x4 days. Kindly ensure con meds used for AE are updated in EDC. Thank you.' answered with 'Per patient, she was prescribed Doxycycline but she did not take it. ' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 21:07:06
User opened query 'Per source it is noted that subject received doxycycline x4 days. Kindly ensure con meds used for AE are updated in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:49:57
User opened query 'Per source subject received juvaderm, kindly update con meds data in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:46:33
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:44:53

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE, PRODUCTSYNONYM: CLOBETASOL 0.05% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:11:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:11:33
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:06:10 28 Oct 2020 17:05:31
User entered 'CLOBETASOL 0.05%' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:05:31
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:53:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:53:44
Data point term sent to Coder User entered 'clobetasol'	System Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:31 28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'PSORIASIS'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the no. Of applications (dose=1, unit=applications). Update as appropriate. Otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:36:12
Query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the no. Of applications (dose=1, unit=applications). Update as appropriate. Otherwise provide clarification' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:05:38
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:05:31
User opened query 'Per DM CLR: Note, 0.05% is a concentration, please update medication name to include this concentration and update dose and dose unit with the no. Of applications (dose=1, unit=applications). Update as appropriate. Otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:42:13
User entered '0.05'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'application' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:05:31
User entered 'percentage'	Krishna Shah (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 15:54:29
User entered 'UN UNK 2010' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 15:52:17
User entered 'UN UNK 200' (non-conformant).	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:54:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:54:45
Data point term sent to Coder	System	28 Sep 2020 15:53:34
User entered 'valtrex'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'cold sores'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[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)	28 Sep 2020 15:54:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:54:44
Data point term sent to Coder	System	28 Sep 2020 15:53:35
User entered 'multivitamin'	Krishna Shah (b) (4)	28 Sep 2020 15:53:31
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'supplement'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Dose is UNK mg. Please review if # of tablets taken daily is known and update entry to number of tablets otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:38:34
Query 'Per DM CLR: Dose is UNK mg. Please review if # of tablets taken daily is known and update entry to number of tablets otherwise provide clarification' answered with 'updated' (Site from DM).	Krishna Shah (b) (4)	28 Oct 2020 17:04:46
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:04:38
User opened query 'Per DM CLR: Dose is UNK mg. Please review if # of tablets taken daily is known and update entry to number of tablets otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:42:41
User entered 'unk'	Krishna Shah (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)' reason for change:	Krishna Shah (b) (4)	28 Oct 2020 17:04:38
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Krishna Shah (b) (4)	28 Sep 2020 15:53:31
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:15:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 17:15:43
Data point term sent to Coder	System	28 Sep 2020 15:54:37
User entered 'albuterol MDI'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'exercise induced asthma'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '90'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN UNK 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:15:24
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 Oct 2020 18:15:24
Data point term sent to Coder	System	19 Oct 2020 18:13:53
User entered 'Td'	(b) (4), (b) (6) (b) (4)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Vaccine'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'un Jan 2010'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Jan 2010'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[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)	01 Nov 2020 21:23:07
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 Nov 2020 21:23:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:15:25
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 Oct 2020 18:15:25
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	19 Oct 2020 18:14:54 19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Vaccine'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'un Sep 2019'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Sep 2019'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:14:00

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 16:09:19
Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly.'	Christina Kennelly (b) (4)	17 Nov 2020 18:26:18
answered with 'Patient was given this medicine after she received her first injection. She did not receive her second injection because of the AE' (Site from DM).	(b) (4)	
User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:07:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:30
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 18:15:55
User entered 'Prednisone'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:51:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:50:11
User entered 'Inflammation under eyes bilaterally'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '24-5'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: According to AE#1 Narrative, swelling was resolved with steroids. Please confirm if PREDNISONE is still ongoing. If not, please update ONGOING to No and enter end date. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 16:23:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 18:15:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM VOLUMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:27:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:27:27
Data point term sent to Coder	System	06 Nov 2020 21:11:56
User entered 'Juvederm voluma filler under bilateral eyes.'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cosmetic enhancement'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered 'UN Jun 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jun 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:48:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:48:23
Data point term sent to Coder	System	06 Nov 2020 21:13:58
User entered 'doxycycline'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Swelling under left eye'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:21:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:21:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:05:35

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:55

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	15 Oct 2020 23:57:56

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:55

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	Kelly Woodell (b) (4) (b) (4)	15 Oct 2020 23:57:56

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:21:55

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:51:10
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Krishna Shah (b) (4)	18 Nov 2020 17:25:22
User entered 'SWELLING UNDER LEFT EYE, AE #1' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 17:25:08
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:55:39
User entered 'Swelling under left eye'	Kelly Woodell (b) (4)	15 Oct 2020 23:57:56