

US3822006 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:38:42

All time stamps listed in this document are displayed in GMT

US3822006

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 18:42:15

Generated On: 12 Aug 2021 13:38:42

[Participant ID](#)

US3822006

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

US3822006

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3822006

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
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

US3822006

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3822006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3822006

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Were any significant conditions reported?

Yes ☒

No ☐

US3822006

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Condition	EXERCISE INDUCED ASTHMA
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822006

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Condition	PSORIASIS
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822006

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Condition	COLD SORES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3822006

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3822006

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (xxx.x)	66.3 in
Weight (xxx.x)	121.6 lb
BMI (xxx.x)	19.49020 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822006

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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.

US3822006

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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 ☒

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Height	ND - Not Done
Weight	ND - Not Done

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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

US3822006

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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.

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:11 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	04 AUG 2020 15:11
------------------------------------	-------------------

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	04 AUG 2020 15:20
Nasopharyngeal Swab 2	No		

US3822006

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 12 Aug 2021 13:38:42

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(5)

Generated On: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

Yes <input type="checkbox"/>	
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: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

46 of 1130

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:38:42

Yes <input type="checkbox"/>	
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(5)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 1130

EAB) (1725)

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

Yes <input type="checkbox"/>	
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: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1130

EAB) (1725)

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

Yes <input type="checkbox"/>	
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: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1130

EAB) (1725)

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 SEP 2020

Collection time (00:00-23:59)

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	07:48 (24 HR)
Collection date and time (derived)	2 OCT 2020 07:48

US3822006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:03:47

Generated On: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

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: 12 Aug 2021 13:38:42

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 12:00:43

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: 12 Aug 2021 13:38:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:03:49
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: 12 Aug 2021 13:38:42

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

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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: 12 Aug 2021 13:38:42

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

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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: 12 Aug 2021 13:38:42

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

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:38:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:05:09

Generated On: 12 Aug 2021 13:38:42

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

Data signed: (b) (4) 05 Mar 2021 15:05:09

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 18:42:27

Generated On: 12 Aug 2021 13:38:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 18:42:27

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 18:42:27

Generated On: 12 Aug 2021 13:38:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 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 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 18:42:27

Generated On: 12 Aug 2021 13:38:42

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3822006

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:38:42

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3822006

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:38:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822006

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 18:42:27

Generated On: 12 Aug 2021 13:38:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3822006

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

Form: Unblinding

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

Date of updated informed consent (dd MMM yyyy) 30 DEC 2020

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 30 DEC 2020

Participant randomization assignment mRNA-1273 ☐ Placebo ☒

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3822006

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 18:42:16

Generated On: 12 Aug 2021 13:38:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 DEC 2020
Collection time (00:00-23:59)	11:51 (24 HR)
Collection date and time (derived)	30 DEC 2020 11:51

US3822006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 18:42:16

Generated On: 12 Aug 2021 13:38:42

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

US3822006

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:42:15

Generated On: 12 Aug 2021 13:38:42

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)

Data signed: (b) (4) 12 Mar 2021 18:42:15

Generated On: 12 Aug 2021 13:38:42

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)

21 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 1130

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:42:15

Generated On: 12 Aug 2021 13:38:42

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

112 of 1130

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:42:15

Generated On: 12 Aug 2021 13:38:42

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 18:42:16

Generated On: 12 Aug 2021 13:38:42

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)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

115 of 1130

EAB) (1725)

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

117 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

119 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

121 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

123 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2010
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

125 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication INFLAMMATION UNDER EYES
BILATERALLY

Dose per administration 24

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

127 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

129 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUN 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

Name of Medication DOXYCYCLINE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

131 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

Name of Medication HYALURONIDASE

Prophylaxis Yes ☐
No ☒

Indication SWELLING UNDER EYE,
BILATERAL

Dose per administration 150/900

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

133 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 11 Apr 2021 23:55:19

Generated On: 12 Aug 2021 13:38:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 18:42:16

Generated On: 12 Aug 2021 13:38:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Mar 2021 20:09:09

Generated On: 12 Aug 2021 13:38:42

Date of dosing discontinuation (dd MMM yyyy)	8 SEP 2020
--	------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

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

AE LOG LINE #1

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Mar 2021 18:42:16

Generated On: 12 Aug 2021 13:38:42

Date of study discontinuation/completion (dd MMM yyyy) 30 DEC 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

PATIENT WAS UNABLE TO RECEIVE VACCINE DUE TO AE THEREFORE SHE CHOOSE TO WITHDRAW

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

Audit

US3822006 (Prod: Tryon Medical Partners, PLLC)

US3822006

Form: Participant Creation

Generated On: 12 Aug 2021 13:38:42

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'US3822006'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:36

US3822006

Form: Participant Creation

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:28:06

US3822006

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:37

US3822006

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'SCRN'	System	04 Aug 2020 19:33:23

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:38

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '51'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'YEARS'	System	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '51'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Female (F)'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'I'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:38:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	04 Aug 2020 19:33:39

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'Aug 2020'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '2020'	System	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Amendment 1 (1)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	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).	(b) (4)	
User entered empty.	System	04 Aug 2020 19:34:11
	Kelly Woodell (b) (4)	04 Aug 2020 19:34:11
	(b) (4)	

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:24:37

US3822006

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:38:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:23

US3822006

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:38:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:35:48

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (4), (b) (6)	29 Sep 2020 12:00:50
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. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (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, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'UN UNK 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'Jan 2020'	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '2020'	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:36:13

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'UN UNK 1985'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'Jan 1985'	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '1985'	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:36:40

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'UN UNK 1990'	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'Jan 1990'	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '1990'	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:37:03

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User coded data point as SOC: Social circumstances, HLT: 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.	Coder Import (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

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'un UNK 2005'	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'Jan 2005'	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '2005'	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	08 Oct 2020 14:17:09

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '14:56'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '04 Aug 2020 14:56'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '66.3' in	Kelly Woodell (b) (4)	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: 12 Aug 2021 13:38:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '121.6' lb	Kelly Woodell (b) (4)	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: 12 Aug 2021 13:38:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty; reason for change Data Entry Error	(b) (4) Krishna Shah (b) (4)	28 Oct 2020 17:02:01
User entered 'Oral (Oral)'	(b) (4) Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:01
User entered '64'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'bpm'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:01
User entered '14'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'breaths/min'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:01
User entered '118'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(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).	Krishna Shah (b) (4)	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).	(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).	Kelly Woodell (b) (4)	16 Sep 2020 23:43:02
User entered '56'	(b) (4)	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:38:02

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:28:06

US3822006

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06

US3822006

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:57

US3822006

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:38:57

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (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) (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) (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'UN UNK 2005'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:38:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:39:25

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 01:19:30
User entered 'No (N)' reason for change: Data Entry Error	System	26 Aug 2020 01:19:30
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	26 Aug 2020 01:19:30
User entered empty.	(b) (4)	
	System	06 Aug 2020 14:40:22
	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22
	(b) (4)	

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0' reason for change: Data Entry Error	(b) (4)	
	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
	(b) (4)	

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '0'	Kelly Woodell (b) (4)	06 Aug 2020 14:40:22

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '1' reason for change: Data Entry Error	(b) (4)	
	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
	(b) (4)	

US3822006

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:38:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Children in the home who will be going to college on campus this year' reason for change: Data Entry Error	(b) (4) 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: 12 Aug 2021 13:38:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'VISIT1'	System	04 Aug 2020 19:34:38

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) 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)	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:34:29

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:38:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Aug 2020 19:34:51

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 12 Aug 2021 13:38:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37
	(b) (4)	

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:19
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37
	(b) (4)	

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37
	(b) (4)	

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '14:56'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '98.0' F	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '64'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'bpm'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '14'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'breaths/min'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '118'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (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) (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) (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:19
User entered '66.3' in	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37
	(b) (4)	

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:38:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:02:19
User entered '121.6' lb	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37
	(b) (4)	

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (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) (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

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 10:08:43
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)	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)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '98.9' F	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '60'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'bpm'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '18'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'breaths/min'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '119'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '66'	Kelly Woodell (b) (4)	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	06 Aug 2020 14:43:37

US3822006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:10

US3822006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '15:51'	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '04 Aug 2020 15:51'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'ONCE'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:04:10

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '15:11'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:28

US3822006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '04 Aug 2020'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '15:20'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	06 Aug 2020 14:44:46

US3822006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (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: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	06 Aug 2020 14:44:51

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'Yes (Y)'	System	04 Aug 2020 20:12:42
	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '98.9'	System	04 Aug 2020 20:12:42
	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '04 Aug 2020 16:12'	System	04 Aug 2020 20:12:42
	System	04 Aug 2020 20:12:42

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'Yes (Y)'	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: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '97.1'	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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'Yes (Y)'	System	07 Aug 2020 10:48:15
	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '97.5'	System	07 Aug 2020 10:48:15
	System	07 Aug 2020 10:48:15

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'Yes (Y)'	System	08 Aug 2020 18:28:20
	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '98.2'	System	08 Aug 2020 18:28:20
	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:28:20
	System	08 Aug 2020 18:28:20

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '97.8'	System	11 Aug 2020 01:52:13
	System	11 Aug 2020 01:52:13

US3822006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	System	04 Aug 2020 20:13:16
	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	System	04 Aug 2020 20:13:16
	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '04 Aug 2020 16:13'	System	04 Aug 2020 20:13:16
	System	04 Aug 2020 20:13:16

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	05 Aug 2020 12:06:21
	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '05 Aug 2020 08:06'	System	05 Aug 2020 12:06:21
	System	05 Aug 2020 12:06:21

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'Does not interfere with activity (2)'	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: 12 Aug 2021 13:38:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	07 Aug 2020 10:48:49
	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	07 Aug 2020 10:48:49
	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '07 Aug 2020 06:48'	System	07 Aug 2020 10:48:49
	System	07 Aug 2020 10:48:49

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	System	08 Aug 2020 18:28:47
	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '08 Aug 2020 14:28'	System	08 Aug 2020 18:28:47
	System	08 Aug 2020 18:28:47

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	System	09 Aug 2020 17:14:36
	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	09 Aug 2020 17:14:36
	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (1)'	System	09 Aug 2020 17:14:36
	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '09 Aug 2020 13:14'	System	09 Aug 2020 17:14:36
	System	09 Aug 2020 17:14:36

US3822006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '05 Aug 2020 08:06'	System	05 Aug 2020 12:06:42
	System	05 Aug 2020 12:06:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '06 Aug 2020 06:34'	System	06 Aug 2020 10:34:42
	System	06 Aug 2020 10:34:42

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	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: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '08 Aug 2020 14:29'	System	08 Aug 2020 18:29:03
	System	08 Aug 2020 18:29:03

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'No (N)'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '09 Aug 2020 13:14'	System	09 Aug 2020 17:14:54
	System	09 Aug 2020 17:14:54

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered 'None (0)'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '10 Aug 2020 21:52'	System	11 Aug 2020 01:52:44
	System	11 Aug 2020 01:52:44

US3822006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:38:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '12 Aug 2020'	System	07 Dec 2020 19:14:27
	Kelly Woodell (b) (4)	07 Sep 2020 15:15:05
	(b) (4)	

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 15:15:05

US3822006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:16

US3822006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	07 Sep 2020 15:15:16

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
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 Dec 2020 19:14:27
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	System	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).	Kelly Woodell (b) (4)	07 Sep 2020 15:15:48
User entered '17 Aug 2020'	(b) (4)	
	System	07 Sep 2020 15:15:29
	Kelly Woodell (b) (4)	07 Sep 2020 15:15:29
	(b) (4)	

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 15:15:29

US3822006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:15:52

US3822006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	07 Sep 2020 15:15:52

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '26 Aug 2020'	System	07 Dec 2020 19:14:27
	Kelly Woodell (b) (4)	07 Sep 2020 15:16:05
	(b) (4)	

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 15:16:05

US3822006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 15:16:09

US3822006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	07 Sep 2020 15:16:09

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	14 Dec 2020 20:54:32
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '8 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:56:05
	(b) (4)	

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4)	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'VISIT2'	System	28 Sep 2020 15:56:05

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	System	14 Dec 2020 20:54:32
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '8 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59
	(b) (4)	

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '16:08'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '98.2' F	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '68'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'bpm'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '18'	(b) (4) 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: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '122'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '78'	Krishna Shah (b) (4)	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	28 Sep 2020 15:56:59

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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) (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) (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) (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:18

US3822006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:57:27

US3822006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:27

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Per CDM: Was study treatment given?' as No. Hence please complete the 'Dosing discontinuation' page.' (Site from DM).	(b) (4) (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) (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) (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
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).	(b) (4)	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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:38:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 15:57:40

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '8 Sep 2020'	System	07 Dec 2020 19:14:27
	Krishna Shah (b) (4)	28 Sep 2020 16:00:49
	(b) (4)	

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '16:21'	Krishna Shah (b) (4)	28 Sep 2020 16:00:49

US3822006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '8 Sep 2020'	System	07 Dec 2020 19:14:27
	Krishna Shah (b) (4)	28 Sep 2020 16:01:06
	(b) (4)	

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '16:40'	Krishna Shah (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 16:01:06

US3822006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:01:11

US3822006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	28 Sep 2020 16:01:11

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '15 Sep 2020'	System	07 Dec 2020 19:14:27
	Krishna Shah (b) (4)	28 Sep 2020 16:01:45
	(b) (4)	

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) Krishna Shah (b) (4)	28 Sep 2020 16:01:45

US3822006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:02:05

US3822006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	28 Sep 2020 16:02:05

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '22 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 16:02:26
	(b) (4)	

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:02:26

US3822006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:02:31

US3822006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	28 Sep 2020 16:02:31

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	Krishna Shah (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	Krishna Shah (b) (4)	06 Oct 2020 16:38:28

US3822006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) Krishna Shah (b) (4)	06 Oct 2020 16:38:28
	(b) (4)	

US3822006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:15:48

US3822006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	04 Oct 2020 22:15:48

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	14 Dec 2020 20:54:32
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'VISIT3'	System	04 Oct 2020 22:16:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	14 Dec 2020 20:54:32
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '07:44'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '58'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'bpm'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '18'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'breaths/min'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '91'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '60'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'mmHg'	System	04 Oct 2020 22:16:57

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:28:06

US3822006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:38:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06

US3822006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:17:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:38:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:17:04

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '2 Oct 2020'	System	07 Dec 2020 19:14:27
	(b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered '07:48'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:17:28

US3822006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Feb 2021 19:03:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Oct 2020 22:17:34

US3822006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	04 Oct 2020 22:17:34

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 64'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 71'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered 'Day 78'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:50
Data entry locked.	System	04 Aug 2020 20:04:10
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 20:04:10

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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' User entered '03 Nov 2020 11:34:05'	System	03 Nov 2020 16:34:08
	System	03 Nov 2020 16:34:08

US3822006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:04
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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'	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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-28T12:00:34', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '298c6d74-a3c5-4476-a2ba-d4abdbea9e63'	System	28 Nov 2020 17:00:48
User entered 'No (N)'	System	28 Nov 2020 17:00:48

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-28T12:00:40', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '298c6d74-a3c5-4476-a2ba-d4abdbea9e63'	System	28 Nov 2020 17:00:48
User entered 'No (N)'	System	28 Nov 2020 17:00:48

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-11-28T12:00:43', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '298c6d74-a3c5-4476-a2ba-d4abdbea9e63' User entered '28 Nov 2020 12:00:43'	System	28 Nov 2020 17:00:48
	System	28 Nov 2020 17:00:48

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-12-05T12:03:46', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '457a3716-32cd-46be-b12b-4e63e5bb9e6d'	System	05 Dec 2020 17:03:53
User entered 'No (N)'	System	05 Dec 2020 17:03:53

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-12-05T12:03:47', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '457a3716-32cd-46be-b12b-4e63e5bb9e6d'	System	05 Dec 2020 17:03:53
User entered 'No (N)'	System	05 Dec 2020 17:03:53

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (427E5C20-6A48-442F-8A06-9A150B4F4654)', Time: '2020-12-05T12:03:49', User OID: 'PatientReportedOutcome (US3822006)', ODM File OID: '457a3716-32cd-46be-b12b-4e63e5bb9e6d' User entered '05 Dec 2020 12:03:49'	System	05 Dec 2020 17:03:53
	System	05 Dec 2020 17:03:53

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27

US3822006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:38:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
DataPoint Activated.	System	14 Dec 2020 20:54:32
DataPoint Inactivated.	System	07 Dec 2020 19:14:27
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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:09
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:09
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '26 Oct 2020'	Krishna Shah (b) (4)	28 Oct 2020 17:03:34
	(b) (4)	

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:09
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Oct 2020 17:03:34

US3822006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:05:09
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Oct 2020 17:03:41

US3822006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	28 Oct 2020 17:03:41

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:26:22

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:54:32
User entered '2 Dec 2020'	System	07 Dec 2020 19:14:27
	(b) (4), (b) (6)	07 Dec 2020 13:26:22

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:26:22

US3822006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:26:22

US3822006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 13:26:39

US3822006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'I'	System	07 Dec 2020 13:26:39

US3822006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is reported under Participant Decision Visit/OL- Day 1 visit in PPD portal; however, data is missing in EDC. Kindly review if sample was collected, if Yes, then please consider updating in EDC for the corresponding date (30DEC2020) and updating Swab data under the OL-D1 folder in Central Lab Nasopharyngeal Swab eCRF. Else clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:54:52
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is reported under Participant Decision Visit/OL- Day 1 visit in PPD portal; however, data is missing in EDC. Kindly review if sample was collected, if Yes, then please consider updating in EDC for the corresponding date (30DEC2020) and updating Swab data under the OL-D1 folder in Central Lab Nasopharyngeal Swab eCRF. Else clarify, Thank you' answered with 'data has been entered' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:26:09
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30DEC2020 is reported under Participant Decision Visit/OL- Day 1 visit in PPD portal; however, data is missing in EDC. Kindly review if sample was collected, if Yes, then please consider updating in EDC for the corresponding date (30DEC2020) and updating Swab data under the OL-D1 folder in Central Lab Nasopharyngeal Swab eCRF. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:47:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 19:55:27

US3822006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:55:27

US3822006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:55:27

US3822006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:38:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 19:55:27

US3822006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	19 Feb 2021 14:55:35
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 19:55:16

US3822006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:38:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	19 Feb 2021 14:55:35
User entered 'I'	System	04 Jan 2021 19:55:16

US3822006

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:37:00
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form. Please clarify and update as appropriate.' answered with 'data has been entered' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:39:20
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:46:55
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	11 Jan 2021 20:37:15

US3822006

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered '30 Dec 2020'	Kelly Woodell (b) (4)	11 Jan 2021 20:37:15

US3822006

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	11 Jan 2021 20:37:15

US3822006

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

Form: Visit Date

Generated On: 12 Aug 2021 13:38:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 20:37:15

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered '30 Dec 2020'	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:06:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:34

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 10:22:54
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'Participant didn't receive 2nd dose' (Site from System).	Kelly Woodell (b) (4) (b) (4)	11 Jan 2021 20:45:59
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	11 Jan 2021 20:45:44
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:44:08
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:19
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:07:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 13:06:44
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:39:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:34

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered '30 Dec 2020'	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:18:21
User entered 'Placebo (Placebo)'	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44
	(b) (4)	

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered empty.	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:27
User entered 'No (N)'	Kelly Woodell (b) (4)	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	11 Jan 2021 20:45:44

US3822006

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

Form: Unblinding

Generated On: 12 Aug 2021 13:38:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	11 Jan 2021 20:45:44

US3822006

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:30

US3822006

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:30

US3822006

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '11:51'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:30

US3822006

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '30 Dec 2020 11:51'	System	22 Jan 2021 20:25:30

US3822006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:38:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:42

US3822006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:38:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:42

US3822006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:38:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '00:00'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:25:42

US3822006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '30 Dec 2020 00:00'	System	22 Jan 2021 20:25:42

US3822006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:38:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:03:09

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
Query 'Per CDM: Please review 'Narrative' on AE Log Line 1 'Narrative'. Site reports subject received Juvederm filler 3-months prior to trial initiation; and experienced subsequent Juvederm filler related reaction at dosing which resulted in dosing discontinuation. Please verify data and consider adding previous Juvederm facial cosmetic injection to Medical History log. Per v5.0 of CCGs, on Medical History form, "Record only diseases and conditions that are deemed relevant / significant by the investigator and that started before the Informed Consent was signed." canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:31:55
User opened query 'Per CDM: Please review 'Narrative' on AE Log Line 1 'Narrative'. Site report subject received Juvederm filler 3-months prior to trial initiation; and experienced subsequent Juvederm filler related reaction at dosing which resulted in dosing discontinuation. Please verify data and consider adding previous Juvederm facial cosmetic injection to Medical History log. Per v5.0 of CCGs, on Medical History form, "Record only diseases and conditions that are deemed relevant / significant by the investigator and that started before the Informed Consent was signed." (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 19:10:22
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) (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.	Coder Import (b) (4) (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

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Adverse event](#)

Audit	User	Time (GMT)
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.	Coder Import (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
User entered 'SWELLING UNDER LEFT EYE' reason for change: Data Entry Error	Christina Kennelly (b) (4)	04 Nov 2020 18:22:08
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

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	08 Oct 2020 10:57:02
User entered 'Sweling under left eye'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:58 28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) Krishna Shah (b) (4) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'Start date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '9 Aug 2020'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41
	(b) (4)	

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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).	(b) (4)	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: 12 Aug 2021 13:38:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:24:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 21:00:13
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 21:00:06
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:26:36
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: 12 Aug 2021 13:38:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	14 Dec 2020 21:00:21
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Dec 2020 21:00:21
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Dec 2020 21:00:06
User entered '21 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	14 Dec 2020 21:00:06
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered empty.	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Per CDM: Per sponsor review, please review and confirm Relationship to IP and Relationship to Study Procedure and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 08:46:49
Query 'Per CDM: Per sponsor review, please review and confirm Relationship to IP and Relationship to Study Procedure and update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 21:13:18
User opened query 'Per CDM: Per sponsor review, please review and confirm Relationship to IP and Relationship to Study Procedure and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 21:04:12
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: 12 Aug 2021 13:38:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 21:13:11
User entered 'Related (RELATED)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41
	(b) (4)	

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed 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) (4), (b) (6)	25 Nov 2020 13:22:52
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: 12 Aug 2021 13:38:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '1' reason for change: Data Entry Error	(b) (4) (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: 12 Aug 2021 13:38:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	14 Dec 2020 21:00:21
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) (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) (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Per DM CLR: Narrative indicates that Steroid and Hyaluronic Acid was given as treatment for this condition. However, there is no corresponding ConMed record of Hyaluronic Acid that match the information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:25:15
Query 'Per DM CLR: Narrative indicates that Steroid and Hyaluronic Acid was given as treatment for this condition. However, there is no corresponding ConMed record of Hyaluronic Acid that match the information. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 21:03:23
User opened query 'Per DM CLR: Narrative indicates that Steroid and Hyaluronic Acid was given as treatment for this condition. However, there is no corresponding ConMed record of Hyaluronic Acid that match the information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 00:03:27
User closed 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)	25 Nov 2020 13:23:32
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

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Narrative](#)

Audit	User	Time (GMT)
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)	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)	04 Nov 2020 18:21:56
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '0'	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '1'	System	28 Sep 2020 16:04:41

US3822006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
DataPoint Verified.	(b) (4) (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) (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) (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) (b) (4)	28 Sep 2020 15:44:53

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) 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: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	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: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'PSORIASIS'	(b) (4) 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: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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) (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: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Other (OTHER)'	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: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'application' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	28 Oct 2020 17:05:31
User entered 'percentage'	(b) (4)	
	Krishna Shah (b) (4)	28 Sep 2020 15:52:17
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'as needed (PRN)'	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: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Topical (TOPICAL)'	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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) 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: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN UNK 2010' reason for change: Data Entry Error	System	28 Sep 2020 15:54:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Krishna Shah (b) (4)	28 Sep 2020 15:54:29
User entered 'UN UNK 200' (non-conformant).	(b) (4)	
	System	28 Sep 2020 15:52:17
	Krishna Shah (b) (4)	28 Sep 2020 15:52:17
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	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: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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)	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)	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)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'cold sores'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'I'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'g (g)'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) 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: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'as needed (PRN)'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'UN UNK 2000'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	(b) (4) 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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:52:54

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) Coder Import (b) (4) (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) (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) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	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: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'supplement'	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: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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) (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) (b) (4)	28 Oct 2020 17:04:46
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4) (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) (b) (4)	28 Sep 2020 15:53:31

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Krishna Shah (b) (4)	28 Oct 2020 17:04:38
User entered 'mg (mg)'	(b) (4)	
	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: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once daily (QD)'	(b) (4) 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: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Oral (ORAL)'	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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'UN UNK 2000'	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: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	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: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	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: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) 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: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'exercise induced asthma'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '90'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'ug (ug)'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'as needed (PRN)'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) 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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'UN UNK 2020'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 15:54:06

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) 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)	19 Oct 2020 18:13:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Vaccine'	(b) (4) (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: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'unk'	(b) (4) (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: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mL (mL)'	(b) (4) (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: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once (ONCE)'	(b) (4) (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: 12 Aug 2021 13:38:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'un Jan 2010'	(b) (4) (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: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	(b) (4) (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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'un Jan 2010'	(b) (4) (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: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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 Apr 2021 06:03:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:03:20
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	12 Mar 2021 18:42:16
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: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Vaccine'	(b) (4) (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: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'unk'	(b) (4) (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: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mL (mL)'	(b) (4) (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: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once (ONCE)'	(b) (4) (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: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'un Sep 2019'	(b) (4) (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: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	(b) (4) (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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'un Sep 2019'	(b) (4) (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: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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) (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.' 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).	Christina Kennelly (b) (4) (b) (4)	17 Nov 2020 18:26:18
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:06:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:06:30
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

PRODUCTION RELEASE (v12.003
EAB) (1725)

1046 of 1130

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:51:07
' canceled (Site from DM).		
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.	(b) (4), (b) (6)	24 Nov 2020 07:50:11
' (Site from DM).		
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: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	11 Apr 2021 23:55:19
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and provide scheme of tapering dosis. Please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:35:21
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and provide scheme of tapering dosis. Please update eCRF as appropriate. ' answered with 'unknown scheme of taper dose since patient discontinued. updated with the information that I have currently' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:19:49
Signature has been broken.	(b) (4), (b) (6)	30 Mar 2021 12:17:05
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 12:17:05
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and provide scheme of tapering dosis. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:08:36
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '24-5'	(b) (4) (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: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mg (mg)'	(b) (4) (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: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once daily (QD)'	(b) (4) (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: 12 Aug 2021 13:38:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Oral (ORAL)'	(b) (4) (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: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) (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: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
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: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	(b) (4) (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: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Per CDM: Please verify data and provide an end-date for this CM (else clarify) since end-date for corresponding CM 'Indication' (AE log line 1) is recorded as 21Sep2020. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:39:00
Query 'Per CDM: Please verify data and provide an end-date for this CM (else clarify) since end-date for corresponding CM 'Indication' (AE log line 1) is recorded as 21Sep2020. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:24:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 14:24:45
User opened query 'Per CDM: Please verify data and provide an end-date for this CM (else clarify) since end-date for corresponding CM 'Indication' (AE log line 1) is recorded as 21Sep2020. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 19:28:07
User closed 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)	15 Dec 2020 11:52:15
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.' answered with 'Per patient this is still ongoing.' (Site from DM).	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 21:01:47
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: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:24:45
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: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	(b) (4) (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: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM VOLUMA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 15:56:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 15:56:28
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: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Yes (Y)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Cosmetic enhancement'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'unk'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mL (mL)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once (ONCE)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'UN Jun 2020'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'UN Jun 2020'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	06 Nov 2020 21:11:52

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
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.	(b) (4) Coders 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.	Coders Import (b) (4) (b) (4)	06 Nov 2020 23:48:23
Data point term sent to Coders	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: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Swelling under left eye'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '100'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mg (mg)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once daily (QD)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	System	14 Dec 2020 20:54:32
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '14 Aug 2020'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '17 Aug 2020'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35
	(b) (4)	

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
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: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '804 (804)'	System	06 Nov 2020 21:13:35

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: OTHER HEMATOLOGICAL AGENTS, ATC: OTHER HEMATOLOGICAL AGENTS, ATC: ENZYMES, PRODUCT: HYALURONIDASE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 21:23:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:23:50
Data point term sent to Coder	System	14 Dec 2020 21:04:15
User entered 'Hyaluronidase'	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'SWELLING UNDER EYE, BILATERAL'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '150/900'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'mg (mg)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'once daily (QD)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Oral (ORAL)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '31 Aug 2020'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '0'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '3 Sep 2020'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '1'	System	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '1'	System	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:38:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User entered '804 (804)'	System	14 Dec 2020 21:03:17

US3822006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:38:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 16:05:35

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:42

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:54:32
User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	07 Dec 2020 19:14:27
User entered '8 Sep 2020'	Kelly Woodell (b) (4)	15 Oct 2020 23:57:56

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:42

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'AE (specify) (ADVERSE EVENT)'	Kelly Woodell (b) (4)	15 Oct 2020 23:57:56

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	19 Mar 2021 20:09:09
User closed query 'Per CDM Re-Query: Site response noted; however, please update only the log line (i.e. #1) as per previous query. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:34:50
Query 'Per CDM Re-Query: Site response noted; however, please update only the log line (i.e. #1) as per previous query. Thank you.' answered with 'updated' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	17 Mar 2021 15:44:15
User entered 'AE LOG LINE #1' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	17 Mar 2021 15:44:10
User opened query 'Per CDM Re-Query: Site response noted; however, please update only the log line (i.e. #1) as per previous query. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:16:05
User closed query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:16:05
Query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:46:15
Signature has been broken.	(b) (4), (b) (6)	15 Mar 2021 14:46:08
User entered 'AE log line 1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 14:46:08
User opened query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:36:20

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:42

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: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Mar 2021 13:36:20
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'updated' (Site from DM).	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Patient had filler reaction' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 15:51:29
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:51:00
User closed query 'Per CDM RQ: As per page 44 of CCGs v2.0, kindly record only the exact AE log line number instead of AE term. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:21:02
Query 'Per CDM RQ: As per page 44 of CCGs v2.0, kindly record only the exact AE log line number instead of AE term. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 13:36:04
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4)	15 Dec 2020 15:22:09
User opened query 'Per CDM RQ: As per page 44 of CCGs v2.0, kindly record only the exact AE log line number instead of AE term. Thank you. ' (Site from DM).	(b) (4)	15 Dec 2020 15:22:04
User closed query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:02:29
Query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:02:29
User entered 'SWELLING UNDER EYE, BILATERAL' reason for change: Data Entry Error	Krishna Shah (b) (4)	14 Dec 2020 20:55:34
	(b) (4)	14 Dec 2020 20:55:27

US3822006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 15:00:10
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

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 17:35:13
User closed query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	12 Mar 2021 17:35:13
Query 'Data is required. Please complete.' answered with 'not required yet' (Site from System).	(b) (4)	12 Mar 2021 17:35:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 11:58:42
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4)	14 Dec 2020 20:54:52
User entered '4 Aug 2020'	(b) (4)	14 Dec 2020 20:54:52
	System	14 Dec 2020 20:54:32
	Krishna Shah (b) (4)	14 Dec 2020 20:54:32
	(b) (4)	14 Dec 2020 20:54:32
	Krishna Shah (b) (4)	07 Dec 2020 19:14:27
	(b) (4)	07 Dec 2020 19:14:27

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	12 Mar 2021 17:35:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 11:58:44
Query 'Data is required. Please complete.' answered with 'not required yet' (Site from System).	Krishna Shah (b) (4)	14 Dec 2020 20:54:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	14 Dec 2020 20:54:32
User entered 'AE (specify) (ADVERSE EVENT)'	Krishna Shah (b) (4)	14 Dec 2020 20:54:32
	(b) (4)	
	Krishna Shah (b) (4)	07 Dec 2020 19:14:27
	(b) (4)	

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	12 Mar 2021 17:35:42
User entered 'Patient was unable to receive vaccine due to AE therefore she choose to withdraw' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	12 Mar 2021 17:35:42
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	12 Mar 2021 17:35:13
User entered empty; reason for change Data Entry Error	Krishna Shah (b) (4) (b) (4)	14 Dec 2020 20:54:32
User entered 'AE of SWELLING UNDER EYE, BILATERAL'	Krishna Shah (b) (4) (b) (4)	07 Dec 2020 19:14:27

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	07 Dec 2020 19:14:27

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	07 Dec 2020 19:14:27

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	07 Dec 2020 19:14:27

US3822006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:38:42

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:28:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:42:16
User entered empty.	Krishna Shah (b) (4)	07 Dec 2020 19:14:27