

US3622206 (Prod: University of Miami)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3622206

Form: Participant Creation

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

US3622206

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

US3622206

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input type="radio"/> Male <input checked="" 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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	07:50 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 07:50
Height (<i>xxx.x</i>)	76 in
Weight (<i>xxx.x</i>)	184 lb
BMI (<i>xxx.x</i>)	22.44401 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Sep 2020 13:13:17

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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

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Form: Risk of Exposure

Data signed: (b) (4) 26 Sep 2020 13:13:17

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

What was the date of randomization? (dd MMM yyyy) 19 SEP 2020

What was the participant's randomization number? 146528

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

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)	19 SEP 2020
Time of assessment (00:00-23:59)	07:50 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 07:50
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

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)	19 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 10:05
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:13:17

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Sep 2020 13:13:17

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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) 19 SEP 2020

What was the treatment time? (00:00-23:59) 09:17 (24 HR)

Treatment Date and Time (derived) 19 SEP 2020 09:17

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 SEP 2020
Collection time (00:00-23:59)	07:55 (24 HR)
Collection date and time (derived)	19 SEP 2020 07:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Collection date (dd MMM yyyy)			19 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:00	19 SEP 2020 08:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 10:02

PC Open Date & Time

19 SEP 2020 09:37

PC Close Date & Time

19 SEP 2020 12:07

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	20 SEP 2020 08:44
PC Open Date & Time	19 SEP 2020 13:02
PC Close Date & Time	20 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 14:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

22 SEP 2020 13:22

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 15:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

24 SEP 2020 18:32

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 21:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 09:37

PC Close Date & Time

19 SEP 2020 12:07

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

20 SEP 2020 08:45

PC Open Date & Time

19 SEP 2020 13:02

PC Close Date & Time

20 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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

20 SEP 2020 14:02

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

21 SEP 2020 12:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 13:23

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

23 SEP 2020 15:11

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

24 SEP 2020 18:33

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

25 SEP 2020 21:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 ☐

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 09:37

PC Close Date & Time

19 SEP 2020 12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 ☐

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	20 SEP 2020 08:46
PC Open Date & Time	19 SEP 2020 13:02
PC Close Date & Time	20 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 ☒

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EAB) (1725)

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 14:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 ☒

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:47
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:24
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 15:11
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 ☒

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EAB) (1725)

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:33
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

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EAB) (1725)

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 21:03
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3622206

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:05:56

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:05:56

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:05:55

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:05:55

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 20:10:05

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:10:05

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	VISIT2

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

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)	16 OCT 2020
Time of assessment (00:00-23:59)	07:02 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 07:02
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	09:03 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:03
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

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.

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

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) 16 OCT 2020

What was the treatment time? (00:00-23:59) 08:30 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 08:30

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

US3622206

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

07:25 (24 HR)

Collection date and time (derived)

16 OCT 2020 07:25

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:30	16 OCT 2020 07:30
Nasopharyngeal Swab 2	No		

US3622206

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 16 OCT 2020 09:08

PC Open Date & Time 16 OCT 2020 08:50

PC Close Date & Time 16 OCT 2020 11:20

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 97.8 °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	17 OCT 2020 08:22
PC Open Date & Time	16 OCT 2020 12:15
PC Close Date & Time	17 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 07:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

18 OCT 2020 19:02

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

98.6 °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

20 OCT 2020 12:31

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 14:13

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 03:43

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 09:09

PC Open Date & Time

16 OCT 2020 08:50

PC Close Date & Time

16 OCT 2020 11:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 08:22

PC Open Date & Time

16 OCT 2020 12:15

PC Close Date & Time

17 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 07:42

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

18 OCT 2020 19:03

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

20 OCT 2020 12:32

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 14:13

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

23 OCT 2020 03:44

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 ☐

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 09:10
PC Open Date & Time	16 OCT 2020 08:50
PC Close Date & Time	16 OCT 2020 11:20

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 ☐

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

No ☒

Yes ☐

PC Time stamp	17 OCT 2020 08:23
PC Open Date & Time	16 OCT 2020 12:15
PC Close Date & Time	17 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 ☒

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 07:42
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

90 of 2227

EAB) (1725)

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:03
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

92 of 2227

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

Yes ☐

PC Time stamp

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 ☒

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 12:32
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 ☒

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 14:14
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 ☒

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 03:45
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3622206

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:05:22

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:38:05

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:38:05

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:38:05

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:38:05

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Nov 2020 19:07:51

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 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

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Nov 2020 19:07:51

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	06:00 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 06:00
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622206

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Nov 2020 19:07:51

Generated On: 10 Jun 2021 09:08:05

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.

US3622206

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Nov 2020 19:07:51

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 NOV 2020

Collection time (00:00-23:59)

06:15 (24 HR)

Collection date and time (derived)

13 NOV 2020 06:15

US3622206

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 19:07:51

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 06:06:26
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 07:48:43

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	18 DEC 2020 13:32:19
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	21 DEC 2020 00:01
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Patient Cloud Close Date & Time	25 DEC 2020 23:59
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US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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 <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

04 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

12 JAN 2021 10:57:50

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 00:58:02
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 13:22:55

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 02:42:45

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 04:24:28

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 10:51:22

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 19:27:53

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	03 MAR 2021 02:40:05
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

08 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 08:18:12

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 23:29:46

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 08:45:55

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 15:42:17

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 215

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

26 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2021 00:01
Patient Cloud Close Date & Time	23 JUL 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	16 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	25 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JAN 2022 00:01
Patient Cloud Close Date & Time	14 JAN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Patient Cloud Open Date & Time	24 OCT 2022 00:01
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Patient Cloud Close Date & Time	28 OCT 2022 23:59
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US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

07 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

14 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

[Patient Cloud Open Date & Time](#)

21 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2022 23:59

US3622206

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:08:05

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
No		03 MAR 2021 02:39:45

US3622206

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:12:14

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:12:14

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:21:55

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:10:27

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:10:27

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:10:27

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 APR 2021
Time of assessment (00:00-23:59)	06:33 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 06:33
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)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	84 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622206

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

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.

US3622206

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

06:45 (24 HR)

Collection date and time (derived)

19 APR 2021 06:45

US3622206

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

US3622206

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622206

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:08:05

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"/>

US3622206

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:08:05

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622206

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

Form: Visit Date

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	12 JAN 2021
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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
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US3622206

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:15:30

Generated On: 10 Jun 2021 09:08:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3622206

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	186 lb
BMI (xxx.x)	

US3622206

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	186 lb
BMI (xxx.x)	
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)	12 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:20
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Height	ND - Not Done
Weight	186 lb
BMI (xxx.x)	
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)	12 JAN 2021
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 12:02
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

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

Form: Physical Examination

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

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.

US3622206

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

Form: Exposure

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 11:29

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

US3622206

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

10:32 (24 HR)

Collection date and time (derived)

12 JAN 2021 10:32

US3622206

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	10:40
Collection Date and Time (derived)	12 JAN 2021 10:40

US3622206

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

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:08:57

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3622206

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

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)	9 FEB 2021
Time of assessment (00:00-23:59)	06:15 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 06:15
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 07:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	106 mmHg
Diastolic Blood Pressure units	MMHG

US3622206

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

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.

US3622206

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

What was the treatment time? (00:00-23:59) 07:11 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 07:11

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

US3622206

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:07:34

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:15:08

Generated On: 10 Jun 2021 09:08:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622206

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:15:08

Generated On: 10 Jun 2021 09:08:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622206

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 14:06:28

Generated On: 10 Jun 2021 09:08:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 14:06:28

Generated On: 10 Jun 2021 09:08:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	06:38 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 06:38
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	102 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622206

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 14:06:28

Generated On: 10 Jun 2021 09:08:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3622206

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 14:06:28

Generated On: 10 Jun 2021 09:08:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	06:50 (24 HR)
Collection date and time (derived)	17 MAR 2021 06:50

US3622206

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 14:06:27

Generated On: 10 Jun 2021 09:08:05

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

AEID	USA-US085-2021-MRNA-1273-P30 1000015
Adverse event	OSTEOMYELITIS WITH GAS GANGRENE DISTAL RIGHT MIDDLE PHALANX 2ND DIGIT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	16 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>

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US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

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

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

THE PARTICIPANT WAS
ADMITTED TO THE HOSPITAL
FOR CELLULITIS ON THE RIGHT
FOOT. HE IS CURRENTLY STILL
ADMITTED AND WILL NOTIFY
US WHEN HE IS DISCHARGED.
PENDING MEDICAL RECORDS.

UPDATE: PARTICIPANT WAS
SENT BY PODIATRIST TO THE
ED FOR EVALUATION OF HIS
RIGHT FOOT ON 3/11/2021.

UPON ADMISSION,
PARTICIPANT WAS DIAGNOSED
WITH OSTEOMYELITIS AND
GAS GANGRENE ON HIS RIGHT
FOOT 2ND DIGIT. AMPUTATION
OF INFECTED DIGIT WAS
PERFORMED, AND
PARTICIPANT WAS TREATED
WITH IV ANTIBIOTICS AND
DISCHARGED ON 3/16/2021.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

AEID	
Adverse event	UNCONTROLLED DIABETES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

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 checked="" type="radio"/> Related <input 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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

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 checked="" type="radio"/> Related <input 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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Sep 2020 13:13:17

Generated On: 10 Jun 2021 09:08:05

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

Yes ☒

No ☐

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

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 30

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 1998
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication LEVEMIR

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 60

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:41:07

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	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 1998
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"/>	

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication MVI

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 2018	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication FISH OIL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 2018
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication PROBIOTIC

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 2018	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication AMOXICILLIN/POTASSIUM
CLAV

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS/GANGRENE

Dose per administration 875/125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication PIPERACILLIN
SOD/TAZOBACTAM SOD

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS/GANGRENE

Dose per administration 3.375

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	Intraocular	<input type="radio"/>
	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 checked="" 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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOMYELITIS/GANGRENE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 checked="" 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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	13 MAR 2021	
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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication ENOXAPARIN SODIUM

Prophylaxis Yes ☒
No ☐

Indication PREVENT BLOOD CLOTS

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)	12 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)	12 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication AMLODIPINE BESYLATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)	12 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication (R) FOOT PAIN (RELATED TO
OSTEOMYELITIS/GANGRENE)

Dose per administration 650

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

EVERY 4 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)		11 MAR 2021
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"/>

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication KETOROLAC TROMETHAMINE

Prophylaxis Yes ☐
No ☒

Indication (R) FOOT PAIN (RELATED TO
OSTEOMYELITIS/GANGRENE)

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	Intraocular	<input type="radio"/>
	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 checked="" 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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
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"/>

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication IV FLUIDS FOR HYDRATION

Dose per administration 1000

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

TWICE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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 checked="" 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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
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"/>

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Name of Medication REGULAR INSULIN

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED DIABETES

Dose per administration 8

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
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"/>

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 14:06:28

Generated On: 10 Jun 2021 09:08:05

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 20:41:07

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 MAR 2021	AMPUTATION OF (R) FOOT 2ND DIGIT	Adverse Event	
11 MAR 2021	(R) FOOT X-RAY	Diagnostic	
12 MAR 2021	US BLE'S	Diagnostic	
12 MAR 2021	ECHO 2D W/ DOPPLER	Diagnostic	
12 MAR 2021	EKG @ 617	Diagnostic	
15 MAR 2021	DELAYED WOUND DEBRIDEMENT AND CLOSURE	Adverse Event	
12 MAR 2021	X-RAY POST OP	Adverse Event	
12 MAR 2021	EKG @ 920	Diagnostic	
12 MAR 2021	MRI (R) FOOT	Diagnostic	

US3622206

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:08:05

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US085-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US085-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/MAR/2021 09:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US085-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 14:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US085-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 11:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 20:41:08

Generated On: 10 Jun 2021 09:08:05

SAEID	USA-US085-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 16:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3622206 (Prod: University of Miami)

US3622206

Form: Participant Creation

Generated On: 10 Jun 2021 09:08:05

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:26:15
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'US3622206'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:39:07

US3622206

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:14
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:22:29

US3622206

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:14
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:39:08

US3622206

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:14
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:22:29

US3622206

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'SCRN'	System	19 Sep 2020 13:22:29

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:39:09

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '45'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'YEARS'	System	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered '45'	System	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:08:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:25
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:15

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'Sep 2020'	System	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered '2020'	System	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:06

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:39:08

US3622206

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:08:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'I'	System	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:43:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:08:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:00
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:10:25

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 19:12:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:12:52
Data point term sent to Coder	System	19 Sep 2020 19:11:34
User entered 'Diabetes'	(b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:11
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'Jan 1998'	System	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered '1998'	System	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered empty.	System	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered empty.	System	19 Sep 2020 19:11:30

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '07:50'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered '19 Sep 2020 07:50'	System	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '76' in	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25
DataPoint set to visible.	System	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '184' lb	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25
DataPoint set to visible.	System	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered '22.44401'	System	19 Sep 2020 19:12:25
DataPoint set to visible.	System	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'kg/m2'	System	19 Sep 2020 19:12:25
DataPoint set to visible.	System	19 Sep 2020 13:23:13

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'bpm'	System	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'breaths/min'	System	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'mmHg'	System	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User entered 'mmHg'	System	19 Sep 2020 19:12:25

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54

US3622206

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54

US3622206

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:43
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:37

US3622206

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:43
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:12:37

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:08:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:44:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:13:31

US3622206

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:31

US3622206

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:31

US3622206

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:23:31

US3622206

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'VISIT1'	System	19 Sep 2020 13:23:31

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:44:07

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '146528'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:44:07

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Sep 2020 12:44:07

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05

US3622206

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:14:05
DataPoint set to visible.	System	19 Sep 2020 13:23:06

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '07:50'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '19 Sep 2020 07:50'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '98'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'bpm'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'breaths/min'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '122'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '76'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '10:05'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '19 Sep 2020 10:05'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '92'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'bpm'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'breaths/min'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '134'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '92'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	19 Sep 2020 19:16:08

US3622206

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:48
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:15

US3622206

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:48
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:15

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'MRNA-1273 OR PLACEBO'	System	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '09:17'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '19 Sep 2020 09:17'	System	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:45:59
User entered 'ONCE'	System	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'INTRAMUSCULAR'	System	19 Sep 2020 13:24:01

US3622206

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:54

US3622206

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:54

US3622206

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '07:55'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:16:54

US3622206

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '19 Sep 2020 07:55'	System	19 Sep 2020 19:16:54

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '08:00'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '19 Sep 2020 08:00'	System	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:21
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered empty.	System	19 Sep 2020 19:17:14

US3622206

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:46:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:17:20

US3622206

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	19 Sep 2020 19:17:20

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-19T09:53:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '189a681b-c481-494e-a960-451de6c582e7'	System	19 Sep 2020 14:02:46
User entered 'Yes (Y)'	System	19 Sep 2020 14:02:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-19T10:02:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '189a681b-c481-494e-a960-451de6c582e7' User entered '97.7'	System	19 Sep 2020 14:02:46
	System	19 Sep 2020 14:02:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-19T10:02:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '189a681b-c481-494e-a960-451de6c582e7'	System	19 Sep 2020 14:02:46
User entered 'No (N)'	System	19 Sep 2020 14:02:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-19T10:02:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '189a681b-c481-494e-a960-451de6c582e7'	System	19 Sep 2020 14:02:46
User entered '19 Sep 2020 10:02'	System	19 Sep 2020 14:02:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 09:37'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 12:07'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:42:56', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4617a1a3-3fc1-4b85-91e3-7d6e387cca5a'	System	20 Sep 2020 12:44:09
User entered 'Yes (Y)'	System	20 Sep 2020 12:44:09

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:43:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4617a1a3-3fc1-4b85-91e3-7d6e387cca5a'	System	20 Sep 2020 12:44:09
User entered '98.3'	System	20 Sep 2020 12:44:09

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:43:26', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4617a1a3-3fc1-4b85-91e3-7d6e387cca5a'	System	20 Sep 2020 12:44:09
User entered 'No (N)'	System	20 Sep 2020 12:44:09

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:44:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4617a1a3-3fc1-4b85-91e3-7d6e387cca5a'	System	20 Sep 2020 12:44:09
User entered '20 Sep 2020 08:44'	System	20 Sep 2020 12:44:09

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 2'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:16', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ad4637cf-955a-4080-948e-f86ef9c73cf8'	System	20 Sep 2020 18:01:46
User entered 'Yes (Y)'	System	20 Sep 2020 18:01:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ad4637cf-955a-4080-948e-f86ef9c73cf8'	System	20 Sep 2020 18:01:46
User entered '98.3'	System	20 Sep 2020 18:01:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:35', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ad4637cf-955a-4080-948e-f86ef9c73cf8'	System	20 Sep 2020 18:01:46
User entered 'No (N)'	System	20 Sep 2020 18:01:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ad4637cf-955a-4080-948e-f86ef9c73cf8'	System	20 Sep 2020 18:01:46
User entered '20 Sep 2020 14:01'	System	20 Sep 2020 18:01:46

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 3'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:44:37', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'fa383aa7-4aa2-49f5-8d7b-b0ed20b72a67'	System	21 Sep 2020 16:47:03
User entered 'Yes (Y)'	System	21 Sep 2020 16:47:03

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:44:55', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'fa383aa7-4aa2-49f5-8d7b-b0ed20b72a67'	System	21 Sep 2020 16:47:03
User entered '98.3'	System	21 Sep 2020 16:47:03

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:45:05', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'fa383aa7-4aa2-49f5-8d7b-b0ed20b72a67'	System	21 Sep 2020 16:47:03
User entered 'No (N)'	System	21 Sep 2020 16:47:03

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:45:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'fa383aa7-4aa2-49f5-8d7b-b0ed20b72a67'	System	21 Sep 2020 16:47:03
User entered '21 Sep 2020 12:45'	System	21 Sep 2020 16:47:03

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 4'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:22:21', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '90a05fe3-27b4-4405-ba79-a9974b9045ff'	System	22 Sep 2020 17:22:51
User entered 'Yes (Y)'	System	22 Sep 2020 17:22:51

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:22:33', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '90a05fe3-27b4-4405-ba79-a9974b9045ff'	System	22 Sep 2020 17:22:51
User entered '97.9'	System	22 Sep 2020 17:22:51

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:22:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '90a05fe3-27b4-4405-ba79-a9974b9045ff'	System	22 Sep 2020 17:22:51
User entered 'No (N)'	System	22 Sep 2020 17:22:51

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:22:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '90a05fe3-27b4-4405-ba79-a9974b9045ff'	System	22 Sep 2020 17:22:51
User entered '22 Sep 2020 13:22'	System	22 Sep 2020 17:22:51

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 5'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:09:56', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f8bdf56d-3141-487b-a69d-8a09ca6a94ab'	System	23 Sep 2020 19:11:14
User entered 'Yes (Y)'	System	23 Sep 2020 19:11:14

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f8bdf56d-3141-487b-a69d-8a09ca6a94ab'	System	23 Sep 2020 19:11:14
User entered '98.5'	System	23 Sep 2020 19:11:14

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:19', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f8bdf56d-3141-487b-a69d-8a09ca6a94ab'	System	23 Sep 2020 19:11:14
User entered 'No (N)'	System	23 Sep 2020 19:11:14

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:30', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f8bdf56d-3141-487b-a69d-8a09ca6a94ab'	System	23 Sep 2020 19:11:14
User entered '23 Sep 2020 15:10'	System	23 Sep 2020 19:11:14

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 6'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:32:29', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2837f36-5188-4dcc-a0f0-9ddf1a592b3f'	System	24 Sep 2020 22:32:53
User entered 'Yes (Y)'	System	24 Sep 2020 22:32:53

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:32:38', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2837f36-5188-4dcc-a0f0-9ddf1a592b3f' User entered '98.6'	System	24 Sep 2020 22:32:53
	System	24 Sep 2020 22:32:53

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:32:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2837f36-5188-4dcc-a0f0-9ddf1a592b3f'	System	24 Sep 2020 22:32:53
User entered 'No (N)'	System	24 Sep 2020 22:32:53

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:32:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2837f36-5188-4dcc-a0f0-9ddf1a592b3f' User entered '24 Sep 2020 18:32'	System	24 Sep 2020 22:32:53
	System	24 Sep 2020 22:32:53

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 7'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:05', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '0dd49ed2-a115-4ad4-91ab-0d8c6fab85f1'	System	26 Sep 2020 01:10:49
User entered 'Yes (Y)'	System	26 Sep 2020 01:10:49

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '0dd49ed2-a115-4ad4-91ab-0d8c6fab85f1'	System	26 Sep 2020 01:10:49
User entered '98.4'	System	26 Sep 2020 01:10:49

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:24', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '0dd49ed2-a115-4ad4-91ab-0d8c6fab85f1'	System	26 Sep 2020 01:10:49
User entered 'No (N)'	System	26 Sep 2020 01:10:49

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:29', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '0dd49ed2-a115-4ad4-91ab-0d8c6fab85f1'	System	26 Sep 2020 01:10:49
User entered '25 Sep 2020 21:02'	System	26 Sep 2020 01:10:49

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 09:37'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 12:07'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:44:45', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ae39894b-6a81-435c-9d74-b017926c9583'	System	20 Sep 2020 12:45:17
User entered 'None (1)'	System	20 Sep 2020 12:45:17

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:44:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ae39894b-6a81-435c-9d74-b017926c9583'	System	20 Sep 2020 12:45:17
User entered 'No (N)'	System	20 Sep 2020 12:45:17

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:44:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ae39894b-6a81-435c-9d74-b017926c9583'	System	20 Sep 2020 12:45:17
User entered 'No (N)'	System	20 Sep 2020 12:45:17

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:05', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ae39894b-6a81-435c-9d74-b017926c9583'	System	20 Sep 2020 12:45:17
User entered 'None (1)'	System	20 Sep 2020 12:45:17

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ae39894b-6a81-435c-9d74-b017926c9583'	System	20 Sep 2020 12:45:17
User entered '20 Sep 2020 08:45'	System	20 Sep 2020 12:45:17

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 2'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '286df566-3629-43a7-9cfb-98795ff24f3b'	System	20 Sep 2020 18:02:18
User entered 'None (1)'	System	20 Sep 2020 18:02:18

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:01:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '286df566-3629-43a7-9cfb-98795ff24f3b'	System	20 Sep 2020 18:02:18
User entered 'No (N)'	System	20 Sep 2020 18:02:18

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:03', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '286df566-3629-43a7-9cfb-98795ff24f3b'	System	20 Sep 2020 18:02:18
User entered 'No (N)'	System	20 Sep 2020 18:02:18

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:09', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '286df566-3629-43a7-9cfb-98795ff24f3b'	System	20 Sep 2020 18:02:18
User entered 'None (1)'	System	20 Sep 2020 18:02:18

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:14', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '286df566-3629-43a7-9cfb-98795ff24f3b'	System	20 Sep 2020 18:02:18
User entered '20 Sep 2020 14:02'	System	20 Sep 2020 18:02:18

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 3'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:45:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ec92051c-8341-4e60-90b2-e54edf519abb'	System	21 Sep 2020 16:47:14
User entered 'None (1)'	System	21 Sep 2020 16:47:14

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:45:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ec92051c-8341-4e60-90b2-e54edf519abb'	System	21 Sep 2020 16:47:14
User entered 'No (N)'	System	21 Sep 2020 16:47:14

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ec92051c-8341-4e60-90b2-e54edf519abb'	System	21 Sep 2020 16:47:14
User entered 'No (N)'	System	21 Sep 2020 16:47:14

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:08', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ec92051c-8341-4e60-90b2-e54edf519abb'	System	21 Sep 2020 16:47:14
User entered 'None (1)'	System	21 Sep 2020 16:47:14

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:20', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ec92051c-8341-4e60-90b2-e54edf519abb'	System	21 Sep 2020 16:47:14
User entered '21 Sep 2020 12:46'	System	21 Sep 2020 16:47:14

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 4'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:22:56', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1270f7c3-b584-42f4-8566-f047cdfd593f'	System	22 Sep 2020 17:23:30
User entered 'None (1)'	System	22 Sep 2020 17:23:30

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:03', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1270f7c3-b584-42f4-8566-f047cdfd593f'	System	22 Sep 2020 17:23:30
User entered 'No (N)'	System	22 Sep 2020 17:23:30

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:10', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1270f7c3-b584-42f4-8566-f047cdfd593f'	System	22 Sep 2020 17:23:30
User entered 'No (N)'	System	22 Sep 2020 17:23:30

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1270f7c3-b584-42f4-8566-f047cdfd593f'	System	22 Sep 2020 17:23:30
User entered 'None (1)'	System	22 Sep 2020 17:23:30

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1270f7c3-b584-42f4-8566-f047cdfd593f'	System	22 Sep 2020 17:23:30
User entered '22 Sep 2020 13:23'	System	22 Sep 2020 17:23:30

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 5'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '31232a01-b83c-4c40-9c7c-b8f8ea58474a'	System	23 Sep 2020 19:11:37
User entered 'None (1)'	System	23 Sep 2020 19:11:37

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '31232a01-b83c-4c40-9c7c-b8f8ea58474a'	System	23 Sep 2020 19:11:37
User entered 'No (N)'	System	23 Sep 2020 19:11:37

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:10:54', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '31232a01-b83c-4c40-9c7c-b8f8ea58474a'	System	23 Sep 2020 19:11:37
User entered 'No (N)'	System	23 Sep 2020 19:11:37

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '31232a01-b83c-4c40-9c7c-b8f8ea58474a'	System	23 Sep 2020 19:11:37
User entered 'None (1)'	System	23 Sep 2020 19:11:37

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '31232a01-b83c-4c40-9c7c-b8f8ea58474a'	System	23 Sep 2020 19:11:37
User entered '23 Sep 2020 15:11'	System	23 Sep 2020 19:11:37

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 6'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '451baf2a-291e-44a0-b0ce-11c11313ae99'	System	24 Sep 2020 22:33:21
User entered 'None (1)'	System	24 Sep 2020 22:33:21

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:05', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '451baf2a-291e-44a0-b0ce-11c11313ae99'	System	24 Sep 2020 22:33:21
User entered 'No (N)'	System	24 Sep 2020 22:33:21

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:09', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '451baf2a-291e-44a0-b0ce-11c11313ae99'	System	24 Sep 2020 22:33:21
User entered 'No (N)'	System	24 Sep 2020 22:33:21

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '451baf2a-291e-44a0-b0ce-11c11313ae99'	System	24 Sep 2020 22:33:21
User entered 'None (1)'	System	24 Sep 2020 22:33:21

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '451baf2a-291e-44a0-b0ce-11c11313ae99'	System	24 Sep 2020 22:33:21
User entered '24 Sep 2020 18:33'	System	24 Sep 2020 22:33:21

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 7'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:36', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7ae029c8-b558-4f74-a9f2-552edf33ef13'	System	26 Sep 2020 01:11:10
User entered 'None (1)'	System	26 Sep 2020 01:11:10

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:40', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7ae029c8-b558-4f74-a9f2-552edf33ef13'	System	26 Sep 2020 01:11:10
User entered 'No (N)'	System	26 Sep 2020 01:11:10

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:44', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7ae029c8-b558-4f74-a9f2-552edf33ef13'	System	26 Sep 2020 01:11:10
User entered 'No (N)'	System	26 Sep 2020 01:11:10

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7ae029c8-b558-4f74-a9f2-552edf33ef13'	System	26 Sep 2020 01:11:10
User entered 'None (1)'	System	26 Sep 2020 01:11:10

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7ae029c8-b558-4f74-a9f2-552edf33ef13'	System	26 Sep 2020 01:11:10
User entered '25 Sep 2020 21:02'	System	26 Sep 2020 01:11:10

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 09:37'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 12:07'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:23', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:30', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:35', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:40', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:44', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'None (0)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:45:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered 'No (N)'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T08:46:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f153c8c6-2462-4dca-91e7-13798a256e55'	System	20 Sep 2020 12:46:06
User entered '20 Sep 2020 08:46'	System	20 Sep 2020 12:46:06

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 2'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:24', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:30', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:32', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:34', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:38', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'None (0)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered 'No (N)'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-20T14:02:47', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4d917954-4450-4b84-87e4-f115c0ff15ae'	System	20 Sep 2020 18:02:50
User entered '20 Sep 2020 14:02'	System	20 Sep 2020 18:02:50

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 3'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:38', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:44', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:47', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:51', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:54', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'None (0)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:46:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered 'No (N)'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-21T12:47:02', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5246a8d2-fa0f-4036-8c49-bfdafec26ad8'	System	21 Sep 2020 16:47:35
User entered '21 Sep 2020 12:47'	System	21 Sep 2020 16:47:35

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 4'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:23:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:24:03', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:24:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:24:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'None (0)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:24:22', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered 'No (N)'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-22T13:24:26', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c2ab5bc0-3ebc-4b97-94b3-86cae4d2ad82'	System	22 Sep 2020 17:24:27
User entered '22 Sep 2020 13:24'	System	22 Sep 2020 17:24:27

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 5'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:22', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:31', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:36', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:40', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'None (0)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:50', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered 'No (N)'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-23T15:11:59', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f10d5a5f-258c-4a1b-85b4-e9f61eaff220'	System	23 Sep 2020 19:12:07
User entered '23 Sep 2020 15:11'	System	23 Sep 2020 19:12:07

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 6'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:32', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:34', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:36', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:39', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1' User entered 'None (0)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered 'No (N)'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-24T18:33:46', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a7117aee-b53e-45a8-aab9-c922559a94d1'	System	24 Sep 2020 22:33:49
User entered '24 Sep 2020 18:33'	System	24 Sep 2020 22:33:49

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 7'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:02:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:03', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:08', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:10', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'None (0)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered 'No (N)'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-09-25T21:03:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cfa30d8b-32f5-4048-bffb-ec636bbd5e91'	System	26 Sep 2020 01:11:28
User entered '25 Sep 2020 21:03'	System	26 Sep 2020 01:11:28

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 13:24:01

US3622206

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:25
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Oct 2020 14:21:24

US3622206

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:25
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered '26 Sep 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Oct 2020 14:21:24

US3622206

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:25
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Oct 2020 14:21:24

US3622206

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:25
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	09 Oct 2020 14:21:24
	(b) (4)	

US3622206

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:33
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Yes (Y)'	Junlin Long	09 Oct 2020 14:21:29

US3622206

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	09 Oct 2020 14:21:29

US3622206

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Yes (Y)'	Junlin Long	09 Oct 2020 14:24:47

US3622206

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered '3 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Oct 2020 14:24:47

US3622206

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Oct 2020 14:24:47

US3622206

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:45:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	09 Oct 2020 14:24:47

US3622206

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:00
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Oct 2020 14:24:52

US3622206

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	09 Oct 2020 14:24:52

US3622206

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:21
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:05
User entered 'Yes (Y)'	Junlin Long	12 Oct 2020 19:33:53

US3622206

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:21
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:05
User entered '12 Oct 2020'	Junlin Long (b) (4)	12 Oct 2020 19:33:53

US3622206

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:21
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Oct 2020 19:33:53

US3622206

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:21
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:05
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	12 Oct 2020 19:33:53
	(b) (4)	

US3622206

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:29
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Oct 2020 19:33:44

US3622206

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	12 Oct 2020 19:33:44

US3622206

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:46
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 11:51:32

US3622206

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:46
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	Junlin Long (b) (4)	16 Oct 2020 11:51:32

US3622206

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:46
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	16 Oct 2020 11:51:32

US3622206

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'VISIT2'	System	16 Oct 2020 11:51:32

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '07:02'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '16 Oct 2020 07:02'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '98.6' F	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Oral (Oral)'	Junlin Long (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 20:54:13
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '91'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'bpm'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'breaths/min'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '139'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '93'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '09:03'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '16 Oct 2020 09:03'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '98.4' F	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Oral (Oral)'	Junlin Long (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 20:54:13
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '91'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'bpm'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'breaths/min'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '127'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:42
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '93'	Junlin Long (b) (4)	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	16 Oct 2020 20:54:13

US3622206

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:09
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:23

US3622206

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:47:09
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 20:54:23
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 12:37:58
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 12:37:58
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	Junlin Long (b) (4)	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '08:30'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '16 Oct 2020 08:30'	System	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:46:56
User entered 'ONCE'	System	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 12:37:58

US3622206

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:31
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Oct 2020 20:54:38

US3622206

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:31
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:38

US3622206

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:31
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '07:25'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:38

US3622206

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '16 Oct 2020 07:25'	System	16 Oct 2020 20:54:38

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:45
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '16 Oct 2020'	Junlin Long (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:45
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:45
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '07:30'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '16 Oct 2020 07:30'	System	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:45
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:45
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	16 Oct 2020 20:54:48
	(b) (4)	

US3622206

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered empty.	System	16 Oct 2020 20:54:48

US3622206

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:48:53
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Oct 2020 20:56:02

US3622206

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	16 Oct 2020 20:56:02

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '09171031-a63b-4e49-8d57-5a32d303e7e3'	System	16 Oct 2020 13:08:50
User entered 'Yes (Y)'	System	16 Oct 2020 13:08:50

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '09171031-a63b-4e49-8d57-5a32d303e7e3'	System	16 Oct 2020 13:08:50
User entered '98.4'	System	16 Oct 2020 13:08:50

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:33', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '09171031-a63b-4e49-8d57-5a32d303e7e3'	System	16 Oct 2020 13:08:50
User entered 'No (N)'	System	16 Oct 2020 13:08:50

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:42', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '09171031-a63b-4e49-8d57-5a32d303e7e3'	System	16 Oct 2020 13:08:50
User entered '16 Oct 2020 09:08'	System	16 Oct 2020 13:08:50

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 08:50'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 11:20'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:21:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c8ec46c8-f190-4dc1-86b8-fc9a75d920e7'	System	17 Oct 2020 12:22:26
User entered 'Yes (Y)'	System	17 Oct 2020 12:22:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:04', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c8ec46c8-f190-4dc1-86b8-fc9a75d920e7'	System	17 Oct 2020 12:22:26
User entered '97.8'	System	17 Oct 2020 12:22:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c8ec46c8-f190-4dc1-86b8-fc9a75d920e7'	System	17 Oct 2020 12:22:26
User entered 'No (N)'	System	17 Oct 2020 12:22:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c8ec46c8-f190-4dc1-86b8-fc9a75d920e7'	System	17 Oct 2020 12:22:26
User entered '17 Oct 2020 08:22'	System	17 Oct 2020 12:22:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 12:15'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 2'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:41:37', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'bc1ba06b-041a-4626-b4af-62dd60cc673e'	System	18 Oct 2020 11:42:03
User entered 'Yes (Y)'	System	18 Oct 2020 11:42:03

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:41:47', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'bc1ba06b-041a-4626-b4af-62dd60cc673e'	System	18 Oct 2020 11:42:03
User entered '98.6'	System	18 Oct 2020 11:42:03

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:41:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'bc1ba06b-041a-4626-b4af-62dd60cc673e'	System	18 Oct 2020 11:42:03
User entered 'No (N)'	System	18 Oct 2020 11:42:03

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:41:59', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'bc1ba06b-041a-4626-b4af-62dd60cc673e'	System	18 Oct 2020 11:42:03
User entered '18 Oct 2020 07:41'	System	18 Oct 2020 11:42:03

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 3'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:12', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c12a0e4b-3aa7-48e1-b2b4-5b6e16ecdbfa'	System	18 Oct 2020 23:02:43
User entered 'Yes (Y)'	System	18 Oct 2020 23:02:43

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:29', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c12a0e4b-3aa7-48e1-b2b4-5b6e16ecdbfa'	System	18 Oct 2020 23:02:43
User entered '98.2'	System	18 Oct 2020 23:02:43

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:36', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c12a0e4b-3aa7-48e1-b2b4-5b6e16ecdbfa'	System	18 Oct 2020 23:02:43
User entered 'No (N)'	System	18 Oct 2020 23:02:43

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c12a0e4b-3aa7-48e1-b2b4-5b6e16ecdbfa'	System	18 Oct 2020 23:02:43
User entered '18 Oct 2020 19:02'	System	18 Oct 2020 23:02:43

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 4'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 5'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '128f846d-fefe-4d43-8647-a05e1a8c6522'	System	20 Oct 2020 16:31:45
User entered 'Yes (Y)'	System	20 Oct 2020 16:31:45

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:34', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '128f846d-fefe-4d43-8647-a05e1a8c6522'	System	20 Oct 2020 16:31:45
User entered '98.6'	System	20 Oct 2020 16:31:45

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:39', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '128f846d-fefe-4d43-8647-a05e1a8c6522'	System	20 Oct 2020 16:31:45
User entered 'No (N)'	System	20 Oct 2020 16:31:45

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '128f846d-fefe-4d43-8647-a05e1a8c6522'	System	20 Oct 2020 16:31:45
User entered '20 Oct 2020 12:31'	System	20 Oct 2020 16:31:45

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 6'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:07', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2d75ca6-bf9e-4ea6-81e3-c1d9e05a32db'	System	21 Oct 2020 18:13:26
User entered 'Yes (Y)'	System	21 Oct 2020 18:13:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2d75ca6-bf9e-4ea6-81e3-c1d9e05a32db'	System	21 Oct 2020 18:13:26
User entered '98.7'	System	21 Oct 2020 18:13:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:19', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2d75ca6-bf9e-4ea6-81e3-c1d9e05a32db'	System	21 Oct 2020 18:13:26
User entered 'No (N)'	System	21 Oct 2020 18:13:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:23', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'a2d75ca6-bf9e-4ea6-81e3-c1d9e05a32db'	System	21 Oct 2020 18:13:26
User entered '21 Oct 2020 14:13'	System	21 Oct 2020 18:13:26

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 7'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:43:29', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2c46b245-0d57-49d0-a2dd-c7f06389228d'	System	23 Oct 2020 07:44:09
User entered 'Yes (Y)'	System	23 Oct 2020 07:44:09

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:43:47', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2c46b245-0d57-49d0-a2dd-c7f06389228d' User entered '97.7'	System	23 Oct 2020 07:44:09
	System	23 Oct 2020 07:44:09

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:43:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2c46b245-0d57-49d0-a2dd-c7f06389228d'	System	23 Oct 2020 07:44:09
User entered 'No (N)'	System	23 Oct 2020 07:44:09

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:43:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2c46b245-0d57-49d0-a2dd-c7f06389228d' User entered '23 Oct 2020 03:43'	System	23 Oct 2020 07:44:09
	System	23 Oct 2020 07:44:09

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e713e10a-5c18-4703-87aa-089f1f9dbcea'	System	16 Oct 2020 13:09:20
User entered 'None (1)'	System	16 Oct 2020 13:09:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:08:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e713e10a-5c18-4703-87aa-089f1f9dbcea'	System	16 Oct 2020 13:09:20
User entered 'No (N)'	System	16 Oct 2020 13:09:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:02', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e713e10a-5c18-4703-87aa-089f1f9dbcea'	System	16 Oct 2020 13:09:20
User entered 'No (N)'	System	16 Oct 2020 13:09:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e713e10a-5c18-4703-87aa-089f1f9dbcea'	System	16 Oct 2020 13:09:20
User entered 'None (1)'	System	16 Oct 2020 13:09:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e713e10a-5c18-4703-87aa-089f1f9dbcea'	System	16 Oct 2020 13:09:20
User entered '16 Oct 2020 09:09'	System	16 Oct 2020 13:09:20

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 08:50'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 11:20'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:37', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7d05ffff-8ae8-4ed4-9aaf-a54ea2b668bf'	System	17 Oct 2020 12:22:59
User entered 'None (1)'	System	17 Oct 2020 12:22:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:42', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7d05ffff-8ae8-4ed4-9aaf-a54ea2b668bf'	System	17 Oct 2020 12:22:59
User entered 'No (N)'	System	17 Oct 2020 12:22:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7d05ffff-8ae8-4ed4-9aaf-a54ea2b668bf'	System	17 Oct 2020 12:22:59
User entered 'No (N)'	System	17 Oct 2020 12:22:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:54', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7d05ffff-8ae8-4ed4-9aaf-a54ea2b668bf'	System	17 Oct 2020 12:22:59
User entered 'None (1)'	System	17 Oct 2020 12:22:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:22:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7d05ffff-8ae8-4ed4-9aaf-a54ea2b668bf'	System	17 Oct 2020 12:22:59
User entered '17 Oct 2020 08:22'	System	17 Oct 2020 12:22:59

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 12:15'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 2'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5d0ea90e-e8aa-486a-a166-a89129e5d72e'	System	18 Oct 2020 11:42:26
User entered 'None (1)'	System	18 Oct 2020 11:42:26

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5d0ea90e-e8aa-486a-a166-a89129e5d72e'	System	18 Oct 2020 11:42:26
User entered 'No (N)'	System	18 Oct 2020 11:42:26

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5d0ea90e-e8aa-486a-a166-a89129e5d72e'	System	18 Oct 2020 11:42:26
User entered 'No (N)'	System	18 Oct 2020 11:42:26

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:21', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5d0ea90e-e8aa-486a-a166-a89129e5d72e'	System	18 Oct 2020 11:42:26
User entered 'None (1)'	System	18 Oct 2020 11:42:26

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:24', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5d0ea90e-e8aa-486a-a166-a89129e5d72e'	System	18 Oct 2020 11:42:26
User entered '18 Oct 2020 07:42'	System	18 Oct 2020 11:42:26

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 3'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:47', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '47178624-3f6a-4d9e-9be4-55ed147e3d00'	System	18 Oct 2020 23:03:06
User entered 'None (1)'	System	18 Oct 2020 23:03:06

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '47178624-3f6a-4d9e-9be4-55ed147e3d00'	System	18 Oct 2020 23:03:06
User entered 'No (N)'	System	18 Oct 2020 23:03:06

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:54', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '47178624-3f6a-4d9e-9be4-55ed147e3d00'	System	18 Oct 2020 23:03:06
User entered 'No (N)'	System	18 Oct 2020 23:03:06

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:02:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '47178624-3f6a-4d9e-9be4-55ed147e3d00'	System	18 Oct 2020 23:03:06
User entered 'None (1)'	System	18 Oct 2020 23:03:06

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '47178624-3f6a-4d9e-9be4-55ed147e3d00'	System	18 Oct 2020 23:03:06
User entered '18 Oct 2020 19:03'	System	18 Oct 2020 23:03:06

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 4'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 5'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b47d095-5ad2-4bda-83c7-f12389ad025f'	System	20 Oct 2020 16:32:09
User entered 'None (1)'	System	20 Oct 2020 16:32:09

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:54', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b47d095-5ad2-4bda-83c7-f12389ad025f'	System	20 Oct 2020 16:32:09
User entered 'No (N)'	System	20 Oct 2020 16:32:09

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:31:57', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b47d095-5ad2-4bda-83c7-f12389ad025f'	System	20 Oct 2020 16:32:09
User entered 'No (N)'	System	20 Oct 2020 16:32:09

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b47d095-5ad2-4bda-83c7-f12389ad025f'	System	20 Oct 2020 16:32:09
User entered 'None (1)'	System	20 Oct 2020 16:32:09

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:05', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b47d095-5ad2-4bda-83c7-f12389ad025f' User entered '20 Oct 2020 12:32'	System	20 Oct 2020 16:32:09
	System	20 Oct 2020 16:32:09

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 6'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b60cdea-eebe-4dc8-9b96-1a0058ec88da'	System	21 Oct 2020 18:13:48
User entered 'None (1)'	System	21 Oct 2020 18:13:48

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:33', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b60cdea-eebe-4dc8-9b96-1a0058ec88da'	System	21 Oct 2020 18:13:48
User entered 'No (N)'	System	21 Oct 2020 18:13:48

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:37', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b60cdea-eebe-4dc8-9b96-1a0058ec88da'	System	21 Oct 2020 18:13:48
User entered 'No (N)'	System	21 Oct 2020 18:13:48

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:40', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b60cdea-eebe-4dc8-9b96-1a0058ec88da'	System	21 Oct 2020 18:13:48
User entered 'None (1)'	System	21 Oct 2020 18:13:48

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '5b60cdea-eebe-4dc8-9b96-1a0058ec88da'	System	21 Oct 2020 18:13:48
User entered '21 Oct 2020 14:13'	System	21 Oct 2020 18:13:48

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 7'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:04', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c7785a8a-e4f6-4ed8-af16-141c2ab23b8f'	System	23 Oct 2020 07:44:29
User entered 'None (1)'	System	23 Oct 2020 07:44:29

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:09', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c7785a8a-e4f6-4ed8-af16-141c2ab23b8f'	System	23 Oct 2020 07:44:29
User entered 'No (N)'	System	23 Oct 2020 07:44:29

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c7785a8a-e4f6-4ed8-af16-141c2ab23b8f'	System	23 Oct 2020 07:44:29
User entered 'No (N)'	System	23 Oct 2020 07:44:29

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c7785a8a-e4f6-4ed8-af16-141c2ab23b8f'	System	23 Oct 2020 07:44:29
User entered 'None (1)'	System	23 Oct 2020 07:44:29

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c7785a8a-e4f6-4ed8-af16-141c2ab23b8f' User entered '23 Oct 2020 03:44'	System	23 Oct 2020 07:44:29
	System	23 Oct 2020 07:44:29

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:33', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:38', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:45', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:50', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'None (0)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:09:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered 'No (N)'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-16T09:10:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '45b356bf-e43d-4ada-93a1-02db1f93a8b3'	System	16 Oct 2020 13:10:07
User entered '16 Oct 2020 09:10'	System	16 Oct 2020 13:10:07

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 08:50'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 11:20'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:10', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:20', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:23', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'None (0)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:31', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered 'No (N)'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-17T08:23:35', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'f0d0d801-8b4e-40aa-91b5-3d6ef6894ff5'	System	17 Oct 2020 12:23:35
User entered '17 Oct 2020 08:23'	System	17 Oct 2020 12:23:35

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '16 Oct 2020 12:15'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 2'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:32', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:35', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:39', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:41', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:44', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:46', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'None (0)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered 'No (N)'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T07:42:55', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4cba1a48-f0d7-438d-9a5b-d55ba765cd1e'	System	18 Oct 2020 11:42:59
User entered '18 Oct 2020 07:42'	System	18 Oct 2020 11:42:59

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 3'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:09', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:16', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'None (0)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:24', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered 'No (N)'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-18T19:03:27', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '05b05d7d-3818-401a-9790-6dcd19e13bd5'	System	18 Oct 2020 23:03:29
User entered '18 Oct 2020 19:03'	System	18 Oct 2020 23:03:29

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 4'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 5'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:10', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:15', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:20', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:22', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'None (0)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:25', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered 'No (N)'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-20T12:32:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e5f96120-91f2-43e8-820e-cc747eb3cfec'	System	20 Oct 2020 16:32:33
User entered '20 Oct 2020 12:32'	System	20 Oct 2020 16:32:33

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 6'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:52', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:13:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:14:01', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:14:04', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:14:06', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'None (0)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:14:09', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered 'No (N)'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-21T14:14:13', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '2a94cfa9-e89f-41d8-96c9-92f867142eb7'	System	21 Oct 2020 18:14:17
User entered '21 Oct 2020 14:14'	System	21 Oct 2020 18:14:17

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
Data entry locked.	System	16 Oct 2020 12:37:58
User entered 'Day 7'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:34', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:37', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:42', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:45', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:50', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'None (0)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

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 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:44:58', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered 'No (N)'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-10-23T03:45:07', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'cf1f2842-48c7-470b-ae50-d9cc791c0c52'	System	23 Oct 2020 07:45:11
User entered '23 Oct 2020 03:45'	System	23 Oct 2020 07:45:11

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 12:37:58

US3622206

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:08:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:54
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 12:37:58

US3622206

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:49:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long	23 Oct 2020 17:15:26

US3622206

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:49:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered '23 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	23 Oct 2020 17:15:26

US3622206

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:49:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	23 Oct 2020 17:15:26

US3622206

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:49:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	23 Oct 2020 17:15:26
	(b) (4)	

US3622206

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:49:29
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:05:23
User entered 'Yes (Y)'	Junlin Long (b) (4)	23 Oct 2020 17:15:30

US3622206

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	23 Oct 2020 17:15:30

US3622206

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:03
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Nov 2020 14:46:29

US3622206

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:03
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered '30 Oct 2020'	Junlin Long (b) (4)	02 Nov 2020 14:46:29

US3622206

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:03
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	02 Nov 2020 14:46:29

US3622206

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:03
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered empty.	Junlin Long (b) (4)	02 Nov 2020 14:46:29

US3622206

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:10
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Nov 2020 14:46:33

US3622206

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	02 Nov 2020 14:46:33

US3622206

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Nov 2020 13:58:18

US3622206

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered '6 Nov 2020'	Junlin Long (b) (4)	10 Nov 2020 13:58:18

US3622206

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	10 Nov 2020 13:58:18

US3622206

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:29
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered empty.	Junlin Long (b) (4)	10 Nov 2020 13:58:18

US3622206

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:50:43
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Nov 2020 13:58:59

US3622206

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	10 Nov 2020 13:58:59

US3622206

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:05
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Nov 2020 12:13:45

US3622206

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:05
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '13 Nov 2020'	Junlin Long (b) (4)	13 Nov 2020 12:13:45

US3622206

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:05
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	13 Nov 2020 12:13:45

US3622206

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'VISIT3'	System	13 Nov 2020 12:13:45

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '13 Nov 2020'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '06:00'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '13 Nov 2020 06:00'	System	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '97.7' F	(b) (4) Junlin Long (b) (4) (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Oral (Oral)'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered empty.	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '99'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'bpm'	System	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '18'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'breaths/min'	System	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '142'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:21
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '92'	Junlin Long (b) (4)	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'mmHg'	System	13 Nov 2020 12:14:14

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39

US3622206

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39

US3622206

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'No (N)'	Junlin Long (b) (4)	13 Nov 2020 12:14:22

US3622206

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered empty.	Junlin Long (b) (4)	13 Nov 2020 12:14:22

US3622206

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Nov 2020 12:14:31

US3622206

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '13 Nov 2020'	Junlin Long (b) (4)	13 Nov 2020 12:14:31

US3622206

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered '06:15'	Junlin Long (b) (4)	13 Nov 2020 12:14:31

US3622206

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered '13 Nov 2020 06:15'	System	13 Nov 2020 12:14:31

US3622206

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 14:51:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:07:51
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Nov 2020 12:14:34

US3622206

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	13 Nov 2020 12:14:34

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22
Data entry locked.	System	19 Sep 2020 13:24:01
User entered 'Day 64'	System	19 Sep 2020 13:24:01

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Have you been exposed to someone with 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 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Please 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)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Please 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)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[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)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Please 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)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22
Data entry locked.	System	19 Sep 2020 13:24:01
User entered '19 Nov 2020 00:01'	System	19 Sep 2020 13:24:01

US3622206

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:45:22
Data entry locked.	System	19 Sep 2020 13:24:01
User entered '23 Nov 2020 23:59'	System	19 Sep 2020 13:24:01

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-11-30T06:05:29', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '728ec71f-4fa6-4eac-9df1-9bc0b0ccb90e'	System	30 Nov 2020 11:06:35
User entered 'No (N)'	System	30 Nov 2020 11:06:35

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-11-30T06:05:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '728ec71f-4fa6-4eac-9df1-9bc0b0ccb90e'	System	30 Nov 2020 11:06:35
User entered 'Yes (Y)'	System	30 Nov 2020 11:06:35

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-11-30T06:05:55', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '728ec71f-4fa6-4eac-9df1-9bc0b0ccb90e'	System	30 Nov 2020 11:06:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 11:06:35

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-11-30T06:06:26', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '728ec71f-4fa6-4eac-9df1-9bc0b0ccb90e'	System	30 Nov 2020 11:06:35
User entered '30 Nov 2020 06:06:26'	System	30 Nov 2020 11:06:35

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-11T07:48:17', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd99999e4-7c98-4566-bb55-8895b9677494'	System	11 Dec 2020 12:48:46
User entered 'No (N)'	System	11 Dec 2020 12:48:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-11T07:48:33', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd99999e4-7c98-4566-bb55-8895b9677494'	System	11 Dec 2020 12:48:46
User entered 'No (N)'	System	11 Dec 2020 12:48:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-11T07:48:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd99999e4-7c98-4566-bb55-8895b9677494'	System	11 Dec 2020 12:48:46
User entered '11 Dec 2020 07:48:43'	System	11 Dec 2020 12:48:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-18T13:31:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ff4efc89-476d-4f77-b39a-af7dfb18a23c'	System	18 Dec 2020 18:32:25
User entered 'No (N)'	System	18 Dec 2020 18:32:25

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-18T13:32:03', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ff4efc89-476d-4f77-b39a-af7dfb18a23c'	System	18 Dec 2020 18:32:25
User entered 'No (N)'	System	18 Dec 2020 18:32:25

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (245b0798c0aa9060)', Time: '2020-12-18T13:32:19', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'ff4efc89-476d-4f77-b39a-af7dfb18a23c'	System	18 Dec 2020 18:32:25
User entered '18 Dec 2020 13:32:19'	System	18 Dec 2020 18:32:25

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-12T10:57:31', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '877e35c6-5849-490f-90bf-9ab81a023b05'	System	12 Jan 2021 15:57:54
User entered 'No (N)'	System	12 Jan 2021 15:57:54

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-12T10:57:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '877e35c6-5849-490f-90bf-9ab81a023b05'	System	12 Jan 2021 15:57:54
User entered 'No (N)'	System	12 Jan 2021 15:57:54

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-12T10:57:50', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '877e35c6-5849-490f-90bf-9ab81a023b05'	System	12 Jan 2021 15:57:54
User entered '12 Jan 2021 10:57:50'	System	12 Jan 2021 15:57:54

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-18T00:57:43', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1436238b-7bfd-41b8-b4d1-655202f14798'	System	18 Jan 2021 05:58:13
User entered 'No (N)'	System	18 Jan 2021 05:58:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-18T00:57:51', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1436238b-7bfd-41b8-b4d1-655202f14798'	System	18 Jan 2021 05:58:13
User entered 'Yes (Y)'	System	18 Jan 2021 05:58:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-18T00:57:55', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1436238b-7bfd-41b8-b4d1-655202f14798'	System	18 Jan 2021 05:58:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 05:58:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-18T00:58:02', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '1436238b-7bfd-41b8-b4d1-655202f14798'	System	18 Jan 2021 05:58:13
User entered '18 Jan 2021 00:58:02'	System	18 Jan 2021 05:58:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-26T13:22:40', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4f25aca3-c3a9-4cec-8846-1daf04c50ede'	System	26 Jan 2021 19:40:59
User entered 'No (N)'	System	26 Jan 2021 19:40:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-26T13:22:48', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4f25aca3-c3a9-4cec-8846-1daf04c50ede'	System	26 Jan 2021 19:40:59
User entered 'No (N)'	System	26 Jan 2021 19:40:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-01-26T13:22:55', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4f25aca3-c3a9-4cec-8846-1daf04c50ede' User entered '26 Jan 2021 13:22:55'	System	26 Jan 2021 19:40:59

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-01T02:42:32', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '81bf5b8a-8c70-4435-9bcf-eba2ea87eb58'	System	01 Feb 2021 07:42:46
User entered 'No (N)'	System	01 Feb 2021 07:42:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-01T02:42:39', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '81bf5b8a-8c70-4435-9bcf-eba2ea87eb58'	System	01 Feb 2021 07:42:46
User entered 'No (N)'	System	01 Feb 2021 07:42:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-01T02:42:45', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '81bf5b8a-8c70-4435-9bcf-eba2ea87eb58'	System	01 Feb 2021 07:42:46
User entered '01 Feb 2021 02:42:45'	System	01 Feb 2021 07:42:46

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-08T04:24:18', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '669d96bc-a2ca-43a7-ae05-dece715c3fc7'	System	08 Feb 2021 09:24:28
User entered 'No (N)'	System	08 Feb 2021 09:24:28

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-08T04:24:22', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '669d96bc-a2ca-43a7-ae05-dece715c3fc7'	System	08 Feb 2021 09:24:28
User entered 'No (N)'	System	08 Feb 2021 09:24:28

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-08T04:24:28', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '669d96bc-a2ca-43a7-ae05-dece715c3fc7'	System	08 Feb 2021 09:24:28
User entered '08 Feb 2021 04:24:28'	System	08 Feb 2021 09:24:28

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-15T10:51:11', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '335e3902-79c5-4974-a6bd-3d94eb02c52e'	System	15 Feb 2021 15:51:23
User entered 'No (N)'	System	15 Feb 2021 15:51:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-15T10:51:16', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '335e3902-79c5-4974-a6bd-3d94eb02c52e'	System	15 Feb 2021 15:51:23
User entered 'No (N)'	System	15 Feb 2021 15:51:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-15T10:51:22', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '335e3902-79c5-4974-a6bd-3d94eb02c52e' User entered '15 Feb 2021 10:51:22'	System	15 Feb 2021 15:51:23
	System	15 Feb 2021 15:51:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-23T19:27:45', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c5f8a86c-d7d5-40dd-be44-ddd537051704'	System	24 Feb 2021 00:27:56
User entered 'No (N)'	System	24 Feb 2021 00:27:56

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-23T19:27:49', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c5f8a86c-d7d5-40dd-be44-ddd537051704'	System	24 Feb 2021 00:27:56
User entered 'No (N)'	System	24 Feb 2021 00:27:56

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-02-23T19:27:53', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'c5f8a86c-d7d5-40dd-be44-ddd537051704'	System	24 Feb 2021 00:27:56
User entered '23 Feb 2021 19:27:53'	System	24 Feb 2021 00:27:56

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-03T02:39:55-05:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8bee792-8a10-450b-8b9f-0f6e868c6fea' User entered 'No (N)'	System	03 Mar 2021 07:40:07
	System	03 Mar 2021 07:40:07

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-03T02:40:01-05:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8bee792-8a10-450b-8b9f-0f6e868c6fea'	System	03 Mar 2021 07:40:07
User entered 'No (N)'	System	03 Mar 2021 07:40:07

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-03T02:40:05-05:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8bee792-8a10-450b-8b9f-0f6e868c6fea' User entered '03 Mar 2021 02:40:05'	System	03 Mar 2021 07:40:07
	System	03 Mar 2021 07:40:07

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-15T08:18:03-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd5a8d56a-ddc8-4ca8-bef1-1d9cfa8508d7'	System	15 Mar 2021 12:18:13
User entered 'No (N)'	System	15 Mar 2021 12:18:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-15T08:18:07-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd5a8d56a-ddc8-4ca8-bef1-1d9cfa8508d7'	System	15 Mar 2021 12:18:13
User entered 'No (N)'	System	15 Mar 2021 12:18:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-15T08:18:12-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'd5a8d56a-ddc8-4ca8-bef1-1d9cfa8508d7'	System	15 Mar 2021 12:18:13
User entered '15 Mar 2021 08:18:12'	System	15 Mar 2021 12:18:13

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-22T23:29:28-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4829d0ce-179a-41bc-ae0c-6b3994358eb1' User entered 'No (N)'	System	23 Mar 2021 03:29:49
	System	23 Mar 2021 03:29:49

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-22T23:29:40-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4829d0ce-179a-41bc-ae0c-6b3994358eb1' User entered 'No (N)'	System	23 Mar 2021 03:29:49
	System	23 Mar 2021 03:29:49

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-22T23:29:46-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '4829d0ce-179a-41bc-ae0c-6b3994358eb1' User entered '22 Mar 2021 23:29:46'	System	23 Mar 2021 03:29:49
	System	23 Mar 2021 03:29:49

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-05T08:45:44-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8dea18d-241a-453d-8d14-c47cf6f99177'	System	05 Apr 2021 12:46:00
User entered 'No (N)'	System	05 Apr 2021 12:46:00

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-05T08:45:50-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8dea18d-241a-453d-8d14-c47cf6f99177'	System	05 Apr 2021 12:46:00
User entered 'No (N)'	System	05 Apr 2021 12:46:00

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-05T08:45:55-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: 'e8dea18d-241a-453d-8d14-c47cf6f99177'	System	05 Apr 2021 12:46:00
User entered '05 Apr 2021 08:45:55'	System	05 Apr 2021 12:46:00

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-12T15:42:07-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7bf01fff-77af-4a97-adf0-7ed0bf86c6b6'	System	12 Apr 2021 19:42:23
User entered 'No (N)'	System	12 Apr 2021 19:42:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-12T15:42:10-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7bf01fff-77af-4a97-adf0-7ed0bf86c6b6'	System	12 Apr 2021 19:42:23
User entered 'No (N)'	System	12 Apr 2021 19:42:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-04-12T15:42:17-04:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '7bf01fff-77af-4a97-adf0-7ed0bf86c6b6'	System	12 Apr 2021 19:42:23
User entered '12 Apr 2021 15:42:17'	System	12 Apr 2021 19:42:23

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 09:45:22

US3622206

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:08:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:45:22
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 09:45:22

US3622206

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:08:05

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-03T02:39:37-05:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '9a3d42c6-02f1-42a0-8a19-ff4a740c99d2'	System	03 Mar 2021 07:39:49
User entered 'No (N)'	System	03 Mar 2021 07:39:49

US3622206

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:08:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5849bba485e0ac0e)', Time: '2021-03-03T02:39:45-05:00', User OID: 'PatientReportedOutcome (US3622206)', ODM File OID: '9a3d42c6-02f1-42a0-8a19-ff4a740c99d2'	System	03 Mar 2021 07:39:49
User entered '03 Mar 2021 02:39:45'	System	03 Mar 2021 07:39:49

US3622206

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:16:19
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	11 Dec 2020 16:40:10

US3622206

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:16:19
User entered '11 Dec 2020'	Junlin Long (b) (4) (b) (4)	11 Dec 2020 16:40:10

US3622206

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:16:19
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4) (b) (4)	11 Dec 2020 16:40:10

US3622206

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:16:19
User entered empty.	Junlin Long (b) (4) (b) (4)	11 Dec 2020 16:40:10

US3622206

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:16:26
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	11 Dec 2020 16:40:13

US3622206

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:08:39
User entered 'I'	System	11 Dec 2020 16:40:13

US3622206

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:12:53
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 14:17:39

US3622206

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:12:53
User entered '15 Jan 2021'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 14:17:39

US3622206

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:12:53
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	15 Jan 2021 18:44:05
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 14:17:39

US3622206

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:12:53
User entered empty; reason for change New Information	Junlin Long (b) (4) (b) (4)	15 Jan 2021 18:44:05
User entered 'unable to contact; messages left'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 14:17:39

US3622206

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:13:03
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	15 Jan 2021 14:17:42

US3622206

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User entered 'I'	System	15 Jan 2021 14:17:42

US3622206

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:04:05

US3622206

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:55
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:04:05

US3622206

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:05
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:04:05

US3622206

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:05
User closed query 'Please answer the continuing question' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:49:01
Query 'Please answer the continuing question' answered with 'answered' (Site from CRA).	Junlin Long (b) (4)	26 Mar 2021 14:28:12
User opened query 'Please answer the continuing question' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:04:09
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 19:21:55
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 17:04:05

US3622206

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:15
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Mar 2021 14:27:47

US3622206

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User entered 'I'	System	26 Mar 2021 14:27:47

US3622206

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Mar 2021 17:32:43

US3622206

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered '16 Mar 2021'	Junlin Long (b) (4)	26 Mar 2021 17:32:43

US3622206

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Mar 2021 17:32:43

US3622206

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered empty.	Junlin Long (b) (4)	26 Mar 2021 17:32:43

US3622206

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:32
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:10:27
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Mar 2021 17:32:47

US3622206

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:15
User entered 'I'	System	26 Mar 2021 17:32:47

US3622206

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:45:54
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:45:35
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	19 Apr 2021 12:57:36
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	19 Apr 2021 12:57:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 12:57:21

US3622206

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:45:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:45:35
User entered '19 Apr 2021' reason for change: Data	(b) (4), (b) (6)	19 Apr 2021 12:57:36
Entry Error		
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 12:57:21

US3622206

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:45:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:45:35
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	19 Apr 2021 12:57:26
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 12:57:26
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	19 Apr 2021 12:57:21
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 12:57:21

US3622206

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 12:57:21

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '06:33'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 06:33'	System	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '100'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '84'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '66'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 12:58:05

US3622206

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 12:58:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 12:58:11

US3622206

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	19 Apr 2021 12:58:16
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	19 Apr 2021 12:58:11
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 12:58:11

US3622206

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:32

US3622206

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:32

US3622206

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '06:45'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:32

US3622206

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 06:45'	System	19 Apr 2021 12:58:32

US3622206

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:58:37

US3622206

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 12:58:37

US3622206

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

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 16:47:43

US3622206

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

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 16:47:43

US3622206

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

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	12 Jan 2021 16:47:43

US3622206

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

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 16:47:43

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:30
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:44:20

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:44:20

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Placebo (Placebo)'	Junlin Long	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:20:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Placebo (Placebo)'	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 16:47:54
	(b) (4)	

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:20:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Placebo (Placebo)'	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 16:47:54
	(b) (4)	

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '1'	System	12 Jan 2021 16:47:54

US3622206

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

Form: Unblinding

Generated On: 10 Jun 2021 09:08:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '1'	System	12 Jan 2021 16:47:54

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '186' lb	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered empty.	System	12 Jan 2021 17:51:16
DataPoint set to visible.	System	12 Jan 2021 16:47:54

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '186' lb	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered empty.	System	12 Jan 2021 17:51:16
DataPoint set to visible.	System	12 Jan 2021 16:47:54

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16
	(b) (4)	

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '10:20'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '12 Jan 2021 10:20'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '98.5' F	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Oral (Oral)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 17:51:16
	(b) (4)	

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '101'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'bpm'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '18'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'breaths/min'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '137'	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 17:51:16
	(b) (4)	

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '95'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered missing code ND - Not Done.	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '186' lb	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:08:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered empty.	System	12 Jan 2021 17:51:16
DataPoint set to visible.	System	12 Jan 2021 16:47:54

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12:02'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '12 Jan 2021 12:02'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '98' F	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Oral (Oral)'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 17:51:16
	(b) (4)	

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '100'	Junlin Long	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'bpm'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '16'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'breaths/min'	System	12 Jan 2021 17:51:16

US3622206

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '121'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	12 Jan 2021 17:51:16

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:46
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '84'	Junlin Long (b) (4)	12 Jan 2021 17:51:16

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	12 Jan 2021 17:51:16

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'No (N)'	Junlin Long	12 Jan 2021 17:51:27

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:13:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered empty.	Junlin Long (b) (4)	12 Jan 2021 17:51:27

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	12 Jan 2021 16:48:09
	(b) (4)	

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered empty.	Junlin Long (b) (4)	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mRNA-1273'	System	12 Jan 2021 16:48:09
DataPoint set to visible.	System	12 Jan 2021 16:47:54

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '11:29'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '12 Jan 2021 11:29'	System	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:07
User entered 'ONCE'	System	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 16:48:09

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long	12 Jan 2021 17:51:47

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 17:51:47

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '10:32'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Jan 2021 17:51:47

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '12 Jan 2021 10:32'	System	12 Jan 2021 17:51:47

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 17:52:05

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '12 Jan 2021'	Junlin Long (b) (4)	12 Jan 2021 17:52:05

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered '10:40'	Junlin Long (b) (4)	12 Jan 2021 17:52:05

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:08:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '12 Jan 2021 10:40'	System	12 Jan 2021 17:52:05

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Jan 2021 17:52:10

US3622206

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '1'	System	12 Jan 2021 17:52:10

US3622206

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:11

US3622206

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:11

US3622206

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:11

US3622206

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:44:52
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:11

US3622206

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:00
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:21

US3622206

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'I'	System	09 Feb 2021 12:41:21

US3622206

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '1'	System	09 Feb 2021 12:41:21
DataPoint set to visible.	System	09 Feb 2021 12:41:21

US3622206

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:39

US3622206

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:39

US3622206

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:10
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:41:39

US3622206

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'OLD29'	System	09 Feb 2021 12:41:39

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	09 Feb 2021 14:41:14
	(b) (4)	

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '9 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '06:15'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '9 Feb 2021 06:15'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '98.3' F	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Oral (Oral)'	Junlin Long	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '102'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'bpm'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '16'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'breaths/min'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '116'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '82'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '9 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '07:45'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '9 Feb 2021 07:45'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '97.9' F	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Oral (Oral)'	Junlin Long	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '100'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'bpm'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '18'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'breaths/min'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '166'	(b) (4) Junlin Long (b) (4) (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:17
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '106'	Junlin Long (b) (4)	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	09 Feb 2021 14:41:14

US3622206

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'No (N)'	Junlin Long	09 Feb 2021 14:41:24

US3622206

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:23
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	09 Feb 2021 14:41:24
	(b) (4)	

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

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)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mRNA-1273'	System	09 Feb 2021 12:42:02
DataPoint set to visible.	System	09 Feb 2021 12:41:21

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered '07:11'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '9 Feb 2021 07:11'	System	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:27
User entered 'ONCE'	System	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:08:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 12:42:02

US3622206

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'Yes (Y)'	Junlin Long (b) (4)	09 Feb 2021 14:41:37

US3622206

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'I'	System	09 Feb 2021 14:41:37

US3622206

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:15:08
User entered 'Yes (Y)'	Junlin Long (b) (4)	17 Feb 2021 15:02:43

US3622206

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:15:08
User entered '17 Feb 2021'	Junlin Long (b) (4)	17 Feb 2021 15:02:43

US3622206

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:15:08
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	17 Feb 2021 15:02:43

US3622206

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:08:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:45:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:15:08
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	17 Feb 2021 15:02:43
	(b) (4)	

US3622206

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:01
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:15:08
User entered 'Yes (Y)'	Junlin Long (b) (4)	17 Feb 2021 15:02:46

US3622206

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:08:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'I'	System	17 Feb 2021 15:02:46

US3622206

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:12:58

US3622206

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:12:58

US3622206

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:12:58

US3622206

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:08:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'OLD57'	System	17 Mar 2021 18:12:58

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '06:38'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '17 Mar 2021 06:38'	System	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '102'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'bpm'	System	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'breaths/min'	System	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '149'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:17
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '87'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered 'mmHg'	System	17 Mar 2021 18:13:48

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52

US3622206

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:08:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52

US3622206

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:22
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56

US3622206

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:08:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:22
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:16:56

US3622206

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:14:24

US3622206

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:14:24

US3622206

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:46:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '06:50'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:14:24

US3622206

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:08:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:51:52
User entered '17 Mar 2021 06:50'	System	17 Mar 2021 18:14:24

US3622206

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:08:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 11:43:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 11:43:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:57
User entered 'No (N)'	Junlin Long (b) (4)	14 Dec 2020 14:26:37

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 13:11:15
User entered	System	17 Mar 2021 13:11:11
'USA-US085-2021-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	17 Mar 2021 13:11:11

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Osteomyelitis bacterial, LLT: Osteomyelitis bacterial - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 12:30:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Apr 2021 12:30:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:40:01
Data point term sent to Coder	System	22 Apr 2021 13:53:19
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
Coding entries removed.	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
User entered 'osteomyelitis with gas gangrene distal right middle phalanx 2nd digit' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 13:52:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of foot - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 11:46:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 11:46:51
Data point term sent to Coder	System	16 Mar 2021 11:46:30
User entered 'RIGHT FOOT CELLULITIS'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '11 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:43:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:09:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:09:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:09:01
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:08:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:40:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 15:11:12
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
User entered '16 Mar 2021' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'End date has been updated.' (Site from Safety).	Junlin Long (b) (4)	22 Apr 2021 11:34:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:09:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Apr 2021 18:09:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:08:33
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:08:33
User entered '19 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 18:08:33
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:06:49
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Apr 2021 13:52:43
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		22 Apr 2021 13:52:43
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Mar 2021 11:46:23
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '11 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:40:01
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 15:11:17
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Hospital discharge date has been updated.' (Site from Safety).	Junlin Long (b) (4)	22 Apr 2021 13:53:38
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
User entered '16 Mar 2021' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 13:52:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:06:34
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:16:11
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 13:10:50
	(b) (4), (b) (6)	
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:10:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	16 Mar 2021 11:46:23
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:16:11
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 13:10:50
	(b) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 13:10:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication ONLY, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this if correct. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:05:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:40:01
Query 'Per DM CLR: Other Action Taken = Concomitant Medication ONLY, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this if correct. Else, clarify. ' answered with 'Concomitant procedure has been checked.' (Site from DM).	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:54:12
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:52:43
User entered '1' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 13:52:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication ONLY, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this if correct. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 08:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 15:11:20
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Outcome has been updated.' (Site from Safety).	Junlin Long (b) (4)	22 Apr 2021 11:35:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:09:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	21 Apr 2021 18:09:01
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:07:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per DS, sepsis was presented on admission. Please advise if sepsis meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:12:44
User opened query 'PV Query: Please provide results of echo and ekg ordered during hospitalization. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:12:36
User opened query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:12:29
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:27:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:40:01
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Hospital discharge summary has been sent to the email - Safety_Moderna@iqvia.com.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	22 Apr 2021 17:56:06
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 17:34:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE PARTICIPANT WAS ADMITTED TO THE HOSPITAL FOR CELLULITIS ON THE RIGHT FOOT. HE IS CURRENTLY STILL ADMITTED AND WILL NOTIFY US WHEN HE IS DISCHARGED. PENDING MEDICAL RECORDS. Update: Participant was sent by podiatrist to the ED for evaluation of his right foot on 3/11/2021. Upon admission, participant was diagnosed with osteomyelitis and gas gangrene on his right foot 2nd digit. Amputation of infected digit was performed, and participant was treated with IV antibiotics and discharged on 3/16/2021.' reason for change: New Information	Junlin Long (b) (4) (b) (4)	22 Apr 2021 17:34:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	22 Apr 2021 15:11:34
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	22 Apr 2021 15:11:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Conmed and conproc pages have been updated.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:56:00
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Participant was tested COVID-19 negative on 11MAR2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:55:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:59:02
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:07:56
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:07:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 16:06:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Mar 2021 11:49:43
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Mar 2021 11:49:43
User entered 'The participant was admitted to the hospital for cellulitis on the right foot. He is currently still admitted and will notify us when he is discharged. Pending medical records.' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 11:49:43
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Mar 2021 11:46:23
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 11:46:23

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus inadequate control, LLT: Diabetes mellitus inadequate control - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:16:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:16:55
Data point term sent to Coder	System	21 Apr 2021 17:49:34
User entered 'uncontrolled diabetes'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:40:01
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 13:39:53
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4)	22 Apr 2021 13:39:53
reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:40:01
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:39:53
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	22 Apr 2021 13:39:53
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Apr 2021 11:37:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	21 Apr 2021 17:49:54
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	21 Apr 2021 17:49:54
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Apr 2021 17:49:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:49:54
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	21 Apr 2021 17:49:19
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:40:01
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		22 Apr 2021 13:39:53
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		22 Apr 2021 13:39:53
User entered '0' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 13:39:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) System	22 Apr 2021 11:37:25
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 11:37:25
User entered '1' reason for change: New Information	(b) (4) Junlin Long (b) (4)	22 Apr 2021 11:37:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:40:01
User entered empty; reason for change New Information	Junlin Long (b) (4)	22 Apr 2021 13:39:53
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 11:37:25
	(b) (4)	
User entered '11 Mar 2021' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 11:37:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 13:39:53
User entered '1'	System	21 Apr 2021 17:49:54
User entered '0'	System	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:49:19

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:35:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:35:53
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 18:05:56
User entered 'hypertension'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 18:05:38

US3622206

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:08:05

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 18:05:38

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:08:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:20
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:14:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:18:01

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 19:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:27:45
Data point term sent to Coder	System	19 Sep 2020 19:26:44
User entered 'Novolog'	(b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Diabetes'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '30'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Units'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:25:46

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 19:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:29:45
Data point term sent to Coder	System	19 Sep 2020 19:28:46
User entered 'LEVEMIR' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Sep 2020 19:28:45
Data point term sent to Coder	System	19 Sep 2020 19:27:46
User entered 'Levimere'	(b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Diabetes'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '60'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Units'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
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)	19 Sep 2020 19:30:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:30:45
Data point term sent to Coder	System	19 Sep 2020 19:29:47
User entered 'MVI'	(b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:29:37

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 19:31:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 19:31:45
Data point term sent to Coder	System	19 Sep 2020 19:30:47
User entered 'Fish oil'	(b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:30:35

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 19:32:46
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 Sep 2020 19:32:46
Data point term sent to Coder	System	19 Sep 2020 19:31:48
User entered 'Probiotic'	(b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 13:15:02
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:13:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Sep 2020 19:31:19

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:09:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:09:17
Data point term sent to Coder	System	22 Apr 2021 14:01:23
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:01:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:42:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:42:42
Data point term sent to Coder	System	21 Apr 2021 18:24:32
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 18:23:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Mar 2021 14:06:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:06:58

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
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 Mar 2021 21:06:58
Data point term sent to Coder	System	17 Mar 2021 18:10:02
User entered 'amoxicillin/potassium clav'	(b) (4), (b) (6) (b) (4)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 14:01:03
User entered 'OSTEOMYLITIS/GANGRENE'	(b) (4)	
reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 14:01:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:23:35
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 18:23:35
User entered 'osteomyelitis/CELLULITIS/gangrene'	(b) (4), (b) (6)	21 Apr 2021 18:23:35
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User closed query 'Per DM CLR: Please review AE eCRF's AE #1 RIGHT FOOT CELLULITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:17:13
Query 'Per DM CLR: Please review AE eCRF's AE #1 RIGHT FOOT CELLULITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:11:18
User opened query 'Per DM CLR: Please review AE eCRF's AE #1 RIGHT FOOT CELLULITIS (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 14:02:15

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'cellulitis'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '875/125'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:09
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 17:28:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:28:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:09
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 17:28:09
User entered '25 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:28:09
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:47:00
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User entered '2'	System	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User entered '1'	System	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:19
User entered '804 (804)'	System	17 Mar 2021 18:09:17

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 14:05:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:05:59
Data point term sent to Coder	System	22 Apr 2021 14:02:24
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:01:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:26:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:26:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
Data point term sent to Coder	System	21 Apr 2021 17:27:51
User entered 'piperacillin sod/tazobactam sod'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 14:01:28
User entered 'OSTEOMYELITIS/GANGRENE'	(b) (4)	22 Apr 2021 14:01:28
reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 14:01:28
DataPoint Verified.	(b) (4)	21 Apr 2021 19:42:51
User entered 'osteomyelitis cellulitis/gangrene'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '3.375'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'g (g)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '1'	System	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '1'	System	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '804 (804)'	System	21 Apr 2021 17:27:22

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 14:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:05:03
Data point term sent to Coder	System	22 Apr 2021 14:02:25
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:01:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 12:24:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 12:24:49
Data point term sent to Coder	System	22 Apr 2021 11:45:14
Coding entries removed.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 11:45:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
Data point term sent to Coder	System	21 Apr 2021 17:30:55
User entered 'vancomycin'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
User entered 'OSTEOMYELITIS/GANGRENE' reason for change: New Information	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:01:40
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 11:45:02
User entered 'OSTEOMYELITIS/CELLULITIS/GANGRENE' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	22 Apr 2021 11:45:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'osteomyelitis cellulitis/ gangrene'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'l'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'g (g)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '13 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User entered '1'	System	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User entered '1'	System	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:31
User entered '804 (804)'	System	21 Apr 2021 17:30:45

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:07:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:07:20
Data point term sent to Coder	System	21 Apr 2021 17:34:00
User entered 'enoxaparin sodium'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'prevent blood clots'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '40'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:33:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 17:33:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:33:09
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:33:09

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:07:19
Data point term sent to Coder User entered 'lisinopril'	System (b) (4), (b) (6)	21 Apr 2021 17:36:08 21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'hypertension'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '20'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:35:21

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:09:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:09:43
Data point term sent to Coder	System	21 Apr 2021 17:37:15
User entered 'amlodipine besylate'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'hypertension'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '10'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:36:11

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 14:04:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 14:04:03
	(b) (4)	
Data point term sent to Coder	System	22 Apr 2021 14:02:25
Coding entries removed.	Junlin Long (b) (4)	22 Apr 2021 14:02:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 19:12:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 19:12:22
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 17:39:17
User entered 'acetaminophen'	(b) (4), (b) (6)	21 Apr 2021 17:38:29
	(b) (4)	

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:02:23
User entered '(R) FOOT PAIN (RELATED TO OSTEOMYELITIS/GANGRENE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:02:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '(r) foot pain (Pain related to cellulitis)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '650'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'other (OTHER)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'every 4 hours'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 17:38:29

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 14:06:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:06:52
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:03:25 22 Apr 2021 14:02:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:43:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:43:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
Data point term sent to Coder User entered 'ketorolac tromethamine'	System (b) (4), (b) (6)	21 Apr 2021 17:40:17 21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 14:02:45
User entered '(R) FOOT PAIN (RELATED TO OSTEOMYELITIS/GANGRENE)' reason for change: New Information	(b) (4) Junlin Long (b) (4) (b) (4)	22 Apr 2021 14:02:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '(r) foot pain (pain related to cellulitis)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '30'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:40:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:40:14
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User entered '1'	System	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User entered '1'	System	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:40
User entered '804 (804)'	System	21 Apr 2021 17:40:02

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 07:14:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:14:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
Data point term sent to Coder	System	21 Apr 2021 17:43:28
User entered 'sodium chloride'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'iv fluids for hydration'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '1000'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'mL (mL)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'other (OTHER)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:44:10
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 11:48:08
User entered 'twice' reason for change: Data Entry Error	(b) (4) Junlin Long (b) (4)	22 Apr 2021 11:48:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '2 doses'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered empty.	System	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered empty.	System	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered empty.	System	21 Apr 2021 17:42:48

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:17:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:17:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:51
Data point term sent to Coder	System	21 Apr 2021 17:45:29
User entered 'regular insulin'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'uncontrolled diabetes'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '8'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'units'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered '16 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User entered '1'	System	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User entered '1'	System	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:08:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:53
User entered '804 (804)'	System	21 Apr 2021 17:44:39

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:08:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:00:03
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 18:09:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 18:09:51
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:34
User entered 'No (N)'	Junlin Long (b) (4)	09 Feb 2021 14:41:52

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:39:21
DataPoint Un-verified.	Junlin Long (b) (4)	22 Apr 2021 11:42:25
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	22 Apr 2021 11:42:25
	(b) (4)	
User entered '12 Mar 2021' reason for change: New Information	Junlin Long (b) (4)	22 Apr 2021 11:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:00:13
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
	(b) (4)	
User entered '13 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 18:11:39

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:00:13
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'amputation of (R) foot 2nd digit'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:11:39

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:00:13
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 18:11:39

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:08:05

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	22 Apr 2021 11:43:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:00:13
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:11:39

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '11 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:11:34

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '(r) foot x-ray'	(b) (4), (b) (6)	21 Apr 2021 18:11:34

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:11:34

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:11:34

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:12:04

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'us ble's'	(b) (4), (b) (6)	21 Apr 2021 18:12:04

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:12:04

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:53
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:12:04

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:12:30

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'echo 2d w/ doppler'	(b) (4), (b) (6)	21 Apr 2021 18:12:30

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:12:30

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:57
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:12:30

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:12:49

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'EKG @ 617'	(b) (4), (b) (6)	21 Apr 2021 18:12:49

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:12:49

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:12:49

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '15 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:13:57

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'delayed wound debridement and closure'	(b) (4), (b) (6)	21 Apr 2021 18:13:57

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Apr 2021 18:13:57

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:13:57

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:08
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:14:51

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:08
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'x-ray post op'	(b) (4), (b) (6)	21 Apr 2021 18:14:51

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:08
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	21 Apr 2021 18:14:51

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:08:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:08
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:14:51

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:15:15

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'ekg @ 920'	(b) (4), (b) (6)	21 Apr 2021 18:15:15

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:15:15

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:15:15

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:08:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:16
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered '12 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 18:47:10

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:08:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:16
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'MRI (R) FOOT'	(b) (4), (b) (6)	21 Apr 2021 18:47:10

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:08:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:16
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	21 Apr 2021 18:47:10

US3622206

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:08:05

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:16
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:39:21
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 18:47:10

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:49
User entered 'USA-US085-2021-MRNA-1273-P301000015'	System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Susanne'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Doblecki-Lewis'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '1120 NW 14th Street'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Miami'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'FL'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '33136'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'US'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 20:28:04
User entered '3'	System	22 Apr 2021 15:12:12
User entered '2'	System	06 Apr 2021 18:09:24
User entered '1'	System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:49
User entered 'USA-US085-2021-MRNA-1273-P301000015'	System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Susanne'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Doblecki-Lewis'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '1120 NW 14th Street'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Miami'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'FL'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '33136'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'US'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 20:28:04
User entered '3'	System	22 Apr 2021 15:12:12
User entered '2'	System	06 Apr 2021 18:09:24
User entered '1'	System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '17/Mar/2021 09:11'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:49
User entered 'USA-US085-2021-MRNA-1273-P301000015'	System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Susanne'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Doblecki-Lewis'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '1120 NW 14th Street'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Miami'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'FL'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '33136'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'US'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 20:28:04
User entered '3'	System	22 Apr 2021 15:12:12
User entered '2'	System	06 Apr 2021 18:09:24
User entered '1'	System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:57:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:15:45
User entered '06/Apr/2021 14:09'	System	06 Apr 2021 18:09:24

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:11:49
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:57:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:15:45
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 18:09:24

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:49
User entered 'USA-US085-2021-MRNA-1273-P301000015'	System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Susanne'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Doblecki-Lewis'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '1120 NW 14th Street'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Miami'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'FL'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '33136'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'US'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 20:28:04
User entered '3'	System	22 Apr 2021 15:12:12
User entered '2'	System	06 Apr 2021 18:09:24
User entered '1'	System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:39:49
User entered '22/Apr/2021 11:12'	System	22 Apr 2021 15:12:12

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:27:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:39:49
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 15:12:12

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:11:49
User entered 'USA-US085-2021-MRNA-1273-P301000015'	System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Yes (Y)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'No (N)'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Susanne'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Doblecki-Lewis'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '1120 NW 14th Street'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'Miami'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'FL'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered '33136'	(b) (4) System	17 Mar 2021 13:11:11

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 10:58:33
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:28
User entered 'US'	(b) (4) System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:08:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 20:28:04
User entered '3'	System	22 Apr 2021 15:12:12
User entered '2'	System	06 Apr 2021 18:09:24
User entered '1'	System	17 Mar 2021 13:11:35

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:08:05

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 11:50:56
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered '22/Apr/2021 16:28'	(b) (4) System	22 Apr 2021 20:28:04

US3622206

Folder: SAE USA-US085-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:08:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 11:50:56
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:28:04