

US3862020 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:59:43

All time stamps listed in this document are displayed in GMT

US3862020

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:04:55

Generated On: 10 Jun 2021 09:59:43

[Participant ID](#)

US3862020

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

US3862020

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3862020

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3862020

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3862020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3862020

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Were any significant conditions reported?

Yes ☒

No ☐

US3862020

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3862020

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3862020

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3862020

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:19
Height (xxx.x)	69.5 in
Weight (xxx.x)	206 lb
BMI (xxx.x)	30.04744 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862020

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3862020

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3862020

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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

Visit date (dd MMM yyyy)	17 AUG 2020
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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	VISIT1
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US3862020

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105203

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 ☒

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Height	69.5 in
Weight	206 lb

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Height	69.5 in
Weight	206 lb
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)	17 AUG 2020
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:19
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Height	69.5 in
Weight	206 lb
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)	17 AUG 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:19
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 14:46 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 14:46

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

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

12:57 (24 HR)

Collection date and time (derived)

17 AUG 2020 12:57

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:43	17 AUG 2020 12:43
Nasopharyngeal Swab 2	No		

US3862020

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

98.7 °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

17 AUG 2020 15:25

PC Open Date & Time

17 AUG 2020 15:06

PC Close Date & Time

17 AUG 2020 17:36

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 98.6 °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	17 AUG 2020 21:55
PC Open Date & Time	17 AUG 2020 18:31
PC Close Date & Time	18 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 21:33

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

98.5 °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

19 AUG 2020 22:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

20 AUG 2020 21:16

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 22:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

22 AUG 2020 21:42

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

98.9 °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

23 AUG 2020 20:57

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

17 AUG 2020 15:26

PC Open Date & Time

17 AUG 2020 15:06

PC Close Date & Time

17 AUG 2020 17:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 AUG 2020 21:56

PC Open Date & Time

17 AUG 2020 18:31

PC Close Date & Time

18 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 AUG 2020 21:34

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

19 AUG 2020 22:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

20 AUG 2020 21:16

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

21 AUG 2020 22:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

22 AUG 2020 21:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 AUG 2020 20:57

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 15:27
PC Open Date & Time	17 AUG 2020 15:06
PC Close Date & Time	17 AUG 2020 17:36

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:56
PC Open Date & Time	17 AUG 2020 18:31
PC Close Date & Time	18 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 ☒

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:35
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 ☒

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:07
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

49 of 2819

EAB) (1725)

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 21:17
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

51 of 2819

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 22:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

53 of 2819

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 ☒

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3862020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:18
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:14
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	074 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	067 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 10:41

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

US3862020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

09:49 (24 HR)

Collection date and time (derived)

16 SEP 2020 09:49

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	09:41	16 SEP 2020 09:41

US3862020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

97.8 °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

16 SEP 2020 11:16

PC Open Date & Time

16 SEP 2020 11:01

PC Close Date & Time

16 SEP 2020 13:31

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

98.5 °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 17 SEP 2020 00:31

PC Open Date & Time 16 SEP 2020 14:26

PC Close Date & Time 17 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:45

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

18 SEP 2020 20:54

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

97.8 °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

19 SEP 2020 20:55

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

98.9 °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

20 SEP 2020 20:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

21 SEP 2020 20:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

98.3 °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

22 SEP 2020 12:49

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 11:18

PC Open Date & Time

16 SEP 2020 11:01

PC Close Date & Time

16 SEP 2020 13:31

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020 00:31

PC Open Date & Time

16 SEP 2020 14:26

PC Close Date & Time

17 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

17 SEP 2020 21:45

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020 20:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

19 SEP 2020 20:56

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020 20:04

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 SEP 2020 20:41

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

22 SEP 2020 12:49

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 11:19
PC Open Date & Time	16 SEP 2020 11:01
PC Close Date & Time	16 SEP 2020 13:31

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 00:32
PC Open Date & Time	16 SEP 2020 14:26
PC Close Date & Time	17 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 ☒

PRODUCTION RELEASE (v12.003

91 of 2819

EAB) (1725)

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:46
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

93 of 2819

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 20:56
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

95 of 2819

EAB) (1725)

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

97 of 2819

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:04
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

99 of 2819

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:42
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 ☒

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:50
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3862020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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	VISIT3

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

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)	09:02 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:02
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	063 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3862020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

16 OCT 2020 09:40

US3862020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:46

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 18:17:42

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 00:02:01

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 00:01:49

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	14 NOV 2020 00:02:24
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 00:03:19

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 14:32:00

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

09 DEC 2020 21:05:45

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 23:30:53

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 DEC 2020 00:03:31
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

31 DEC 2020 18:40:23

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 JAN 2021 08:57:09
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 JAN 2021 14:30:54
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

21 JAN 2021 14:32:02

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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	30 JAN 2021 18:04:23
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:02:18

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

12 FEB 2021 12:54:53

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 10:30:32

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 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	09 APR 2021 12:06:46
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

14 APR 2021 11:35:37

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 21:26:43

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

28 APR 2021 17:37:52

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
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Patient Cloud Close Date & Time	24 APR 2022 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 <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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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="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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	16 OCT 2022 23:59
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US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3862020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:59:43

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		29 MAR 2021 10:41:41

US3862020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:25:13

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:25:13

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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 _____

US3862020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

Visit date (dd MMM yyyy)	02 MAR 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	VISIT4
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US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:05:37

Generated On: 10 Jun 2021 09:59:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 12:06
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3862020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3862020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 21:40:27

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 21:40:27

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862020

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:59:43

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"/>

US3862020

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:59:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3862020

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

Visit date (dd MMM yyyy)	2 MAR 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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US3862020

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	2 MAR 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>)	2 MAR 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

US3862020

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

US3862020

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Height	ND - Not Done
Weight	ND - Not Done
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)	2 MAR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 12:06
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	060 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Height	ND - Not Done
Weight	ND - Not Done
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)	2 MAR 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 14:15
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3862020

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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) 2 MAR 2021

What was the treatment time? (00:00-23:59) 13:40 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 13:40

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

US3862020

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3862020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00 - 23:59)

12:30

Collection Date and Time (derived)

2 MAR 2021 12:30

US3862020

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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

Visit date (dd MMM yyyy)	31 MAR 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	OLD29
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US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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)	31 MAR 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 11:30
Temperature (xxx.x)	098.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	099 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	051 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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)	31 MAR 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 13:30
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	060 mmHg
Diastolic Blood Pressure units	MMHG

US3862020

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 MAR 2021

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

US3862020

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

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) 31 MAR 2021

What was the treatment time? (00:00-23:59) 13:00 (24 HR)

Treatment Date and Time (derived) 31 MAR 2021 13:00

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

US3862020

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862020

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3862020

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

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.

US3862020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3862020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:11:19

Generated On: 10 Jun 2021 09:59:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

AEID

Adverse event COUGH

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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EAB) (1725)

348 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	COUGH X 1 DAY. DID NOT TAKE ANY MEDICATIONS AND SYMPTOM DID NOT INTERFERE WITH DAILY ACTIVITIES.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

AEID

Adverse event

CHEST PAIN NON CARDIAC

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

350 of 2819

EAB) (1725)

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

AEID	
Adverse event	IRON DEFICIENCY ANEMIA
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)	30 OCT 2020
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 checked="" type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

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 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) _____	

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

AEID	USA-US121-2021-MRNA-1273-P30 1000001
Adverse event	MEDULLARY GASTRIC ADENOCARCINOMA STAGE III
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)	04 JAN 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 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	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	
PRODUCTION RELEASE (v12.003 EAB) (1725)	354 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

20JAN2021

THE SUBJECT WAS
UNDERGOING HIS ANNUAL
CHECK UP IN DEC 2020 AND
FOUND TO BE ANEMIC. AS
PART OF ANEMIA W/U, EGD
WAS DONE ON 04JAN2021.
ULCERS IN HIS STOMACH
WERE IDENTIFIED AND
BIOPSIES WERE TAKEN WHICH
REVEALED GASTRIC CANCER.
HE IS SCHEDULED ON 3RD OF
FEB TO GET CT ABD AND US
GUIDED EGD.

IN DEC, HE WAS FEELING
UNUSUALLY TIRED, HAD
VAGUE PAIN IN CHEST AREA
AND THAT IS WHAT PROMPTED
THE EVALUATION. HE LOST
~10LBS LATELY BUT HAS ALSO
BEEN EATING BETTER AND
EXERCISING. HIS (b) (6)
ALSO HAD A DX OF GASTRIC
CANCER @ AGE 77. BEING
EVALUATED FOR GENETIC
PREDISPOSITION

A/P SAE OF GASTRIC CA:
UNRELATED TO STUDY
VACCINE.

AGREED TO SIGN A RELEASE
OF INFORMATION SO WE CAN
OBTAIN THE MEDICAL
RECORDS AND DISCUSS WITH

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

HIS DOCTORS.

10 MAR 2021: MEDICAL
RECORDS REVIEWED
SUBJECT HAD DIAGNOSTIC
LAPAROSCOPY ON 19 FEB 2021:
GASTRIC MASS ATTACHED TO
LEFT LOBE OF LIVER AND
TRANSVERSE COLON

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)	

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

AEID

Adverse event

UNCONTROLLED TYPE 2
DIABETES MELLITUS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

358 of 2819

EAB) (1725)

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

AEID

Adverse event

HYPOCALCEMIA

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

29 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

29 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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)	_____

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

AEID	USA-US121-2021-MRNA-1273-P30 1000009
Adverse event	SEVERE ANEMIA
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)	28 APR 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 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)	28 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

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	PARTICIPANT ADMITED TO THE HOSPITAL WITH LOW HEMOGLOBIN LEVEL ON 28 APR 2021. HE WILL BE DISCHARGED ON 30 APR 2021.MEDICAL RECORDS WILL BE REQUESTED AFTER THE DISCHARGE DAY.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:04:59

Generated On: 10 Jun 2021 09:59:43

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

Yes ☒

No ☐

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

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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)

372 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

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

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 JAN 2021	
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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication IRON SUPPLEMENT

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FERRIC CARBOXYMALTOSE
INFUSION

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 750

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)

378 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	13 JAN 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 JAN 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication COLONOSCOPY

Dose per administration 175

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
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"/>	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication COLONOSCOPY

Dose per administration 7

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
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"/>	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ENDOSCOPY

Dose per administration 100

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
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"/>	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication VERSED

Prophylaxis Yes ☐

No ☒

Indication ENDOSCOPY

Dose per administration 4

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☐

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☒

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☐

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

PRODUCTION RELEASE (v12.003

386 of 2819

EAB) (1725)

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
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"/>	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication GOLYTELY BOWEL PREP

Prophylaxis Yes ☐
No ☒

Indication COLONOSCOPY

Dose per administration 400

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

388 of 2819

EAB) (1725)

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)		03 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 JAN 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication PACKED RED BLOOD CELL
BLOOD TRANSFUSION

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 250

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)

390 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 JAN 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED TYPE 2
DIABETES MELLITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)		13 JAN 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication PAIN POST PORTHA CATH
INSERTION

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication EMPLA CREAM 2.5%

Prophylaxis Yes ☐
No ☒

Indication PORTH-A-CATH ACCESS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

396 of 2819

EAB) (1725)

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 FEB 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

398 of 2819

EAB) (1725)

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	13 JAN 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication CHEMOTHERAPY
INDUCED-NAUSEA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

400 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	22 FEB 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication CHEMOTHERAPY
INDUCED-NAUSEA

Dose per administration 8

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 8 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	22 FEB 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL NEUROPATHY

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN JUN 2019		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
HEARTBURN

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 ☐

PRODUCTION RELEASE (v12.003

406 of 2819

EAB) (1725)

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)		17 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FLUOROURACIL

Prophylaxis Yes ☐
No ☒

Indication MEDULLARY GASTRIC
ADENOCARCINOMA STAGE III

Dose per administration 4,800

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

CONTINUOUS INFUSION VIA
PORT CATH FOR 48 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 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)		31 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication PACKED RBC TRANSFUSSION

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNIT

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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) 29 MAR 2021		
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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication CALCIUM GLUCONATE

Prophylaxis Yes ☐
No ☒

Indication HYPOCALCEMIA

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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) 29 MAR 2021		
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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication MEDULLARY GASTRIC STAGE
III ADENOCARCINOMA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication FERRIC CARBOXYMALTOSE

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 750

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	29 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)	29 MAR 2021	
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"/>	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication 0.9% SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOCALCEMIA

Dose per administration 50

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

ADMINISTRED WITH CALCIUM
GLUCONATE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication 0.9% SODOIM GLUCONATE

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 250

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

ADMINISTRED WITH FERRIC
CARBOXYMALTOSE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication LEUCOVORIN

Prophylaxis Yes ☐
No ☒

Indication MEDULLARY GASTRIC III
ADENOCARCINOMA

Dose per administration 800

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)

422 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication OXALIPLATIN

Prophylaxis Yes ☐
No ☒

Indication MEDULLARY GASTRIC III
ADENOCARCINOMA

Dose per administration 170

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)

424 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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)	29 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)		29 MAR 2021
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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication PALONOSETRON

Prophylaxis Yes ☐
No ☒

Indication MEDULLARY GASTRIC III
ADENOCARCINOMA

Dose per administration 0.25

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)

426 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

Name of Medication MAGNEZIUM SULFATE

Prophylaxis Yes ☒
No ☐

Indication CHEMOTHERAPY INDUCED
NEPHROTOXICITY
PROPHYLAXIS

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 2819

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 16:54:03

Generated On: 10 Jun 2021 09:59:43

	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 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)	29 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)		29 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"/>

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:05:36

Generated On: 10 Jun 2021 09:59:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 14:05:35

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 FEB 2021	DIAGNOSTIC LAPAROSCOPY	Adverse Event	
19 FEB 2021	PORT PLACEMENT	Adverse Event	
04 FEB 2021	UPPER ENDOSCOPY	Adverse Event	
04 FEB 2021	GASTRIC BIOPSY	Adverse Event	
20 FEB 2021	MRI ABDOMEN	Adverse Event	
22 JAN 2021	CT OF CHEST, ABDOMEN AND PELVIS	Adverse Event	
04 JAN 2021	ESOPHAGOGASTRODUODENOSCOPY WITH BIOPSY	Adverse Event	
04 JAN 2021	COLONOSCOPY WITH BIOPSY	Adverse Event	
04 JAN 2021	MODERATE SEDATION	Adverse Event	
22 FEB 2021	PET/CT SCAN SKULL BASE TO MID THIGH	Adverse Event	

US3862020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:59:43

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3862020

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:59:43

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 ☐

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/JAN/2021 10:05
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.	True

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/MAR/2021 11:53
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/MAR/2021 12:20
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/MAR/2021 09:32
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:52
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/MAR/2021 14:04
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Apr 2021 18:32:18

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/APR/2021 06:12
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

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 19:17:45

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000009
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 19:17:45

Generated On: 10 Jun 2021 09:59:43

SAEID	USA-US121-2021-MRNA-1273-P301000009
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	03/MAY/2021 12:00
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

US3862020 (Prod: Baylor College of Medicine)

US3862020

Form: Participant Creation

Generated On: 10 Jun 2021 09:59:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'US3862020'	RWS_ENDPOINT	17 Aug 2020 17:54:21
	ENDPOINT (b) (4)	

US3862020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 18:07:02
	(b) (4)	

US3862020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:54:23

US3862020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	17 Aug 2020 18:07:02
	(b) (4)	

US3862020

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'SCRN'	System	17 Aug 2020 18:07:02

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:54:24

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '61'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'YEARS'	System	17 Aug 2020 18:08:55

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '61'	System	17 Aug 2020 18:09:19

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Male (M)'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'I'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 18:08:55
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'Aug 2020'	System	17 Aug 2020 18:09:19

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2020'	System	17 Aug 2020 18:09:19

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Amendment 2 (2)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:19
	(b) (4)	

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:54:23

US3862020

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '1'	System	17 Aug 2020 18:09:22

US3862020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:22
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:59:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:22:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:28
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:24:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:24:20
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:24:05
User entered 'diabetes mellitus type 2'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'un UNK 2010'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:18
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'Jan 2010'	System	17 Aug 2020 23:23:18

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2010'	System	17 Aug 2020 23:23:18

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:18

US3862020

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:18

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
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)	17 Aug 2020 23:24:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:24:20
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:24:05
User entered 'hypertension'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'un UNK 2018'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:23:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 23:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:23:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:23:39
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:39
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'Jan 2018'	System	17 Aug 2020 23:23:39

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2018'	System	17 Aug 2020 23:23:39

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:39

US3862020

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:39

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:24:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:24:20
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:24:05
User entered 'hyperlipidemia'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'un Mar 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:23:59
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'Mar 2020'	System	17 Aug 2020 23:23:59

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2020'	System	17 Aug 2020 23:23:59

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:59

US3862020

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:23:59

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:26:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 23:26:22
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:25:05
User entered 'benign prostatic hyperplasia'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'un Mar 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:19
	(b) (4)	

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'Mar 2020'	System	17 Aug 2020 23:24:19

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2020'	System	17 Aug 2020 23:24:19

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:24:19

US3862020

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	17 Aug 2020 23:24:19

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12:19'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '17 Aug 2020 12:19'	System	17 Aug 2020 23:14:44

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '69.5' in	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 18:09:22

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '206' lb	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 18:09:22

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
Amendment Manager: User entered '30.04744'	System	17 Sep 2020 00:00:23
User entered '30.0'	System	17 Aug 2020 23:14:44
DataPoint set to visible.	System	17 Aug 2020 18:09:22

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'kg/m2'	System	17 Aug 2020 23:14:44
DataPoint set to visible.	System	17 Aug 2020 18:09:22

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '97.8' F	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Other (Other)'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'TEMPORAL'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '76'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'bpm'	System	17 Aug 2020 23:14:44

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'breaths/min'	System	17 Aug 2020 23:14:44

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '134'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	17 Aug 2020 23:14:44

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '70'	Carrie Kibler (b) (4)	17 Aug 2020 23:14:44
	(b) (4)	

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	17 Aug 2020 23:14:44

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42

US3862020

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42

US3862020

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:44
	(b) (4)	

US3862020

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	23 Sep 2020 20:00:35
User entered '17 Aug 2020' reason for change: Data Entry Error	Trent Davis (b) (4)	23 Sep 2020 20:00:35
	(b) (4)	
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	23 Sep 2020 19:59:48
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:48
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4)	23 Sep 2020 19:59:48
	(b) (4)	
Comment added 'Screening and enrollment was on the same day with PE'.	Chanei Henry (b) (4)	16 Sep 2020 23:39:52
	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 14:59:51
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:44
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

[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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

[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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:16:21
	(b) (4)	
User entered '1'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

[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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:16:21
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:15:52
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:39

US3862020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:39
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	17 Aug 2020 18:09:39

US3862020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'VISIT1'	System	17 Aug 2020 18:09:39

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:06:46

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:04:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:04:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:06:46
User entered '105203' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:06:46

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:06:46

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:18:21

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:18:21

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:18:21

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:12:27
Query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. ' answered with 'Reported.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	03 Nov 2020 19:04:13
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:14:05
Query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Nov 2020 18:13:58
Comment added 'request was made in IRT to update stratification'.	Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:35:10
User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile. (Site from System).	System	17 Aug 2020 23:18:21
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:18:21

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:18:21

US3862020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Chanei Henry (b) (4)	21 Sep 2020 20:05:54
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:23:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:41:35

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '69.5' in	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '206' lb	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '69.5' in	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '206' lb	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12:19'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '17 Aug 2020 12:19'	System	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '97.8' F	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Other (Other)'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'temporal'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '76'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'bpm'	System	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'breaths/min'	System	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '134'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '70'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Aug 2020 23:20:13

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '69.5' in	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '206' lb	Carrie Kibler (b) (4)	17 Aug 2020 23:20:13
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:54:29
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:20:59
User entered '15:19'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '17 Aug 2020 15:19'	System	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '98.7' F	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:21:23
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:20:59
User entered 'Other (Other)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'temporal' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:21:23
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:21:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 23:21:23
User entered '76' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:21:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 23:20:59
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'bpm'	System	17 Aug 2020 23:21:23
User entered empty.	System	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:21:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 23:21:23
User entered '16' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:21:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 23:20:59
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'breaths/min'	System	17 Aug 2020 23:21:23
User entered empty.	System	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:21:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 23:21:23
User entered '118' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:21:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 23:20:59
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Aug 2020 23:21:23
User entered empty.	System	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:21:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 23:21:23
User entered '72' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:21:23
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:20:59
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Aug 2020 23:21:23
User entered empty.	System	17 Aug 2020 23:20:59

US3862020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:21:32

US3862020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:21:32
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '14:46'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '17 Aug 2020 14:46'	System	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4)	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'ONCE'	System	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:18:02

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 17AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:46:15
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 17AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'PPD reported these samples were received' (Site from DM).	Trent Davis (b) (4) (b) (4)	06 Nov 2020 17:55:11
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 17AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:22:06
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:22:10

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "PPD reported these samples were received", however, the Collection Date recorded in GCL is 10AUG2020 and here it is recorded as 17AUG2020. Please confirm the correct Collection Date and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:35:01
Query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "PPD reported these samples were received", however, the Collection Date recorded in GCL is 10AUG2020 and here it is recorded as 17AUG2020. Please confirm the correct Collection Date and update if appropriate.' answered with 'data is correct' (Site from DM).	Trent Davis (b) (4) (b) (4)	08 Dec 2020 16:42:49
User opened query 'Per GCL Lab Reconciliation: Re-Query: Previous query response indicates, "PPD reported these samples were received", however, the Collection Date recorded in GCL is 10AUG2020 and here it is recorded as 17AUG2020. Please confirm the correct Collection Date and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 15:01:04
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported with date 10Aug2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:46:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported with date 10Aug2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'PPD reported these samples were received' (Site from DM).	Trent Davis (b) (4) (b) (4)	06 Nov 2020 17:55:16

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported with date 10Aug2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you. ' (Site from DM). User entered '17 Aug 2020'	(b) (4), (b) (6)	23 Oct 2020 13:07:13
	Carrie Kibler (b) (4)	17 Aug 2020 23:22:10
	(b) (4)	

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12:57'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:10

US3862020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '17 Aug 2020 12:57'	System	17 Aug 2020 23:22:10

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 17AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is reported as 10AUG2020 in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 19:19:08
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 17AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is reported as 10AUG2020 in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' answered with 'EDC STATES 17AUG2020 DATA IS CORRECT' (Site from DM).	Trent Davis (b) (4)	09 Nov 2020 21:50:29
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 17AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is reported as 10AUG2020 in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:28:48
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12:43'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '17 Aug 2020 12:43'	System	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered empty.	System	17 Aug 2020 23:22:22

US3862020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Chanei Henry (b) (4)	20 Aug 2020 16:21:14

US3862020

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	20 Aug 2020 16:21:14

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:25:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5e1db869-0870-40fc-86f3-2d8be1f53697' User entered 'Yes (Y)'	System	17 Aug 2020 20:25:42
	System	17 Aug 2020 20:25:42

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:25:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5e1db869-0870-40fc-86f3-2d8be1f53697' User entered '98.7'	System	17 Aug 2020 20:25:42
	System	17 Aug 2020 20:25:42

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:25:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5e1db869-0870-40fc-86f3-2d8be1f53697'	System	17 Aug 2020 20:25:42
User entered 'No (N)'	System	17 Aug 2020 20:25:42

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:25:41', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5e1db869-0870-40fc-86f3-2d8be1f53697' User entered '17 Aug 2020 15:25'	System	17 Aug 2020 20:25:42
	System	17 Aug 2020 20:25:42

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 17:36'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:54:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bab1881e-9956-43ec-9796-f965189ce6d3' User entered 'Yes (Y)'	System	18 Aug 2020 02:55:24
	System	18 Aug 2020 02:55:24

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:54:59', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bab1881e-9956-43ec-9796-f965189ce6d3' User entered '98.6'	System	18 Aug 2020 02:55:24
	System	18 Aug 2020 02:55:24

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:04', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bab1881e-9956-43ec-9796-f965189ce6d3' User entered 'No (N)'	System	18 Aug 2020 02:55:24
	System	18 Aug 2020 02:55:24

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bab1881e-9956-43ec-9796-f965189ce6d3' User entered '17 Aug 2020 21:55'	System	18 Aug 2020 02:55:24
	System	18 Aug 2020 02:55:24

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 18:31'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 2'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:32:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ce950f6f-a50c-4fcc-8c52-b39db1cc268a' User entered 'Yes (Y)'	System	19 Aug 2020 02:33:04
	System	19 Aug 2020 02:33:04

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:32:39', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ce950f6f-a50c-4fcc-8c52-b39db1cc268a' User entered '98.2'	System	19 Aug 2020 02:33:04
	System	19 Aug 2020 02:33:04

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:32:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ce950f6f-a50c-4fcc-8c52-b39db1cc268a'	System	19 Aug 2020 02:33:04
User entered 'No (N)'	System	19 Aug 2020 02:33:04

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:33:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ce950f6f-a50c-4fcc-8c52-b39db1cc268a' User entered '18 Aug 2020 21:33'	System	19 Aug 2020 02:33:04
	System	19 Aug 2020 02:33:04

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 3'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:04:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9b8f4909-743c-4f05-a2d5-9657fa244d9d' User entered 'Yes (Y)'	System	20 Aug 2020 03:05:32
	System	20 Aug 2020 03:05:32

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:05:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9b8f4909-743c-4f05-a2d5-9657fa244d9d' User entered '98.5'	System	20 Aug 2020 03:05:32
	System	20 Aug 2020 03:05:32

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:05:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9b8f4909-743c-4f05-a2d5-9657fa244d9d'	System	20 Aug 2020 03:05:32
User entered 'No (N)'	System	20 Aug 2020 03:05:32

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:05:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9b8f4909-743c-4f05-a2d5-9657fa244d9d' User entered '19 Aug 2020 22:05'	System	20 Aug 2020 03:05:32
	System	20 Aug 2020 03:05:32

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 4'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:12:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2799af60-0ea7-4a35-b6b7-8a61f69afb51' User entered 'Yes (Y)'	System	21 Aug 2020 02:16:03
	System	21 Aug 2020 02:16:03

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:15:38', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2799af60-0ea7-4a35-b6b7-8a61f69afb51' User entered '98.4'	System	21 Aug 2020 02:16:03
	System	21 Aug 2020 02:16:03

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:15:44', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2799af60-0ea7-4a35-b6b7-8a61f69afb51' User entered 'No (N)'	System	21 Aug 2020 02:16:03
	System	21 Aug 2020 02:16:03

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2799af60-0ea7-4a35-b6b7-8a61f69afb51' User entered '20 Aug 2020 21:16'	System	21 Aug 2020 02:16:03
	System	21 Aug 2020 02:16:03

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 5'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:00:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8df21ddb-ab63-4acd-9235-fc2b10009f83' User entered 'Yes (Y)'	System	22 Aug 2020 03:03:14
	System	22 Aug 2020 03:03:14

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:02:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8df21ddb-ab63-4acd-9235-fc2b10009f83' User entered '99.1'	System	22 Aug 2020 03:03:14
	System	22 Aug 2020 03:03:14

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:00:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8df21ddb-ab63-4acd-9235-fc2b10009f83' User entered 'No (N)'	System	22 Aug 2020 03:03:14
	System	22 Aug 2020 03:03:14

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:02:38', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8df21ddb-ab63-4acd-9235-fc2b10009f83' User entered '21 Aug 2020 22:02'	System	22 Aug 2020 03:03:14
	System	22 Aug 2020 03:03:14

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 6'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:42:30', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7531ab50-e0b7-4823-aa7b-f32ea7c6ccf0' User entered 'Yes (Y)'	System	23 Aug 2020 02:42:59
	System	23 Aug 2020 02:42:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:42:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7531ab50-e0b7-4823-aa7b-f32ea7c6ccf0' User entered '98.6'	System	23 Aug 2020 02:42:59
	System	23 Aug 2020 02:42:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:42:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7531ab50-e0b7-4823-aa7b-f32ea7c6ccf0' User entered 'No (N)'	System	23 Aug 2020 02:42:59
	System	23 Aug 2020 02:42:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:42:56', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7531ab50-e0b7-4823-aa7b-f32ea7c6ccf0' User entered '22 Aug 2020 21:42'	System	23 Aug 2020 02:42:59
	System	23 Aug 2020 02:42:59

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 7'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:56:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '55926b11-8d6f-4e3e-bf01-56de48005d08' User entered 'Yes (Y)'	System	24 Aug 2020 01:57:09
	System	24 Aug 2020 01:57:09

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:56:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '55926b11-8d6f-4e3e-bf01-56de48005d08' User entered '98.9'	System	24 Aug 2020 01:57:09
	System	24 Aug 2020 01:57:09

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:56:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '55926b11-8d6f-4e3e-bf01-56de48005d08'	System	24 Aug 2020 01:57:09
User entered 'No (N)'	System	24 Aug 2020 01:57:09

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '55926b11-8d6f-4e3e-bf01-56de48005d08' User entered '23 Aug 2020 20:57'	System	24 Aug 2020 01:57:09
	System	24 Aug 2020 01:57:09

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:25:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a361ce8-6950-478e-9c3f-bb30f29cf2d8'	System	17 Aug 2020 20:26:36
User entered 'None (1)'	System	17 Aug 2020 20:26:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a361ce8-6950-478e-9c3f-bb30f29cf2d8'	System	17 Aug 2020 20:26:36
User entered 'No (N)'	System	17 Aug 2020 20:26:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a361ce8-6950-478e-9c3f-bb30f29cf2d8'	System	17 Aug 2020 20:26:36
User entered 'No (N)'	System	17 Aug 2020 20:26:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a361ce8-6950-478e-9c3f-bb30f29cf2d8'	System	17 Aug 2020 20:26:36
User entered 'None (1)'	System	17 Aug 2020 20:26:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:32', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a361ce8-6950-478e-9c3f-bb30f29cf2d8' User entered '17 Aug 2020 15:26'	System	17 Aug 2020 20:26:36
	System	17 Aug 2020 20:26:36

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 17:36'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:30', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7a3ffdf2-77f0-4d21-947f-6d7810dce628'	System	18 Aug 2020 02:56:03
User entered 'None (1)'	System	18 Aug 2020 02:56:03

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7a3ffdf2-77f0-4d21-947f-6d7810dce628'	System	18 Aug 2020 02:56:03
User entered 'No (N)'	System	18 Aug 2020 02:56:03

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7a3ffdf2-77f0-4d21-947f-6d7810dce628'	System	18 Aug 2020 02:56:03
User entered 'No (N)'	System	18 Aug 2020 02:56:03

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:55:51', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7a3ffdf2-77f0-4d21-947f-6d7810dce628'	System	18 Aug 2020 02:56:03
User entered 'None (1)'	System	18 Aug 2020 02:56:03

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7a3ffdf2-77f0-4d21-947f-6d7810dce628'	System	18 Aug 2020 02:56:03
User entered '17 Aug 2020 21:56'	System	18 Aug 2020 02:56:03

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 18:31'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 2'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:33:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a1dccd4-9769-4cd6-adb9-0286e4777946' User entered 'None (1)'	System	19 Aug 2020 02:34:09
	System	19 Aug 2020 02:34:09

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:33:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a1dccc4-9769-4cd6-adb9-0286e4777946' User entered 'No (N)'	System	19 Aug 2020 02:34:09
	System	19 Aug 2020 02:34:09

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:33:35', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a1dccd4-9769-4cd6-adb9-0286e4777946' User entered 'No (N)'	System	19 Aug 2020 02:34:09
	System	19 Aug 2020 02:34:09

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:33:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a1dccd4-9769-4cd6-adb9-0286e4777946' User entered 'None (1)'	System	19 Aug 2020 02:34:09
	System	19 Aug 2020 02:34:09

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a1dccd4-9769-4cd6-adb9-0286e4777946' User entered '18 Aug 2020 21:34'	System	19 Aug 2020 02:34:09
	System	19 Aug 2020 02:34:09

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 3'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:05:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '33f85e72-f266-499f-8318-1ea0b393779b' User entered 'None (1)'	System	20 Aug 2020 03:06:45
	System	20 Aug 2020 03:06:45

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:04', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '33f85e72-f266-499f-8318-1ea0b393779b' User entered 'No (N)'	System	20 Aug 2020 03:06:45
	System	20 Aug 2020 03:06:45

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '33f85e72-f266-499f-8318-1ea0b393779b' User entered 'No (N)'	System	20 Aug 2020 03:06:45
	System	20 Aug 2020 03:06:45

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '33f85e72-f266-499f-8318-1ea0b393779b' User entered 'None (1)'	System	20 Aug 2020 03:06:45
	System	20 Aug 2020 03:06:45

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '33f85e72-f266-499f-8318-1ea0b393779b' User entered '19 Aug 2020 22:06'	System	20 Aug 2020 03:06:45
	System	20 Aug 2020 03:06:45

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 4'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:16', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd1464815-b0c7-44b8-be2b-16c51533d26f' User entered 'None (1)'	System	21 Aug 2020 02:16:51
	System	21 Aug 2020 02:16:51

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd1464815-b0c7-44b8-be2b-16c51533d26f' User entered 'No (N)'	System	21 Aug 2020 02:16:51
	System	21 Aug 2020 02:16:51

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd1464815-b0c7-44b8-be2b-16c51533d26f' User entered 'No (N)'	System	21 Aug 2020 02:16:51
	System	21 Aug 2020 02:16:51

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:45', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd1464815-b0c7-44b8-be2b-16c51533d26f' User entered 'None (1)'	System	21 Aug 2020 02:16:51
	System	21 Aug 2020 02:16:51

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd1464815-b0c7-44b8-be2b-16c51533d26f' User entered '20 Aug 2020 21:16'	System	21 Aug 2020 02:16:51
	System	21 Aug 2020 02:16:51

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 5'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:02:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc186b5d-51ed-4d8b-b58f-00a0428568c1' User entered 'None (1)'	System	22 Aug 2020 03:03:32
	System	22 Aug 2020 03:03:32

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:02:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc186b5d-51ed-4d8b-b58f-00a0428568c1' User entered 'No (N)'	System	22 Aug 2020 03:03:32
	System	22 Aug 2020 03:03:32

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:02', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc186b5d-51ed-4d8b-b58f-00a0428568c1' User entered 'No (N)'	System	22 Aug 2020 03:03:32
	System	22 Aug 2020 03:03:32

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:13', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc186b5d-51ed-4d8b-b58f-00a0428568c1' User entered 'None (1)'	System	22 Aug 2020 03:03:32
	System	22 Aug 2020 03:03:32

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:28', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc186b5d-51ed-4d8b-b58f-00a0428568c1' User entered '21 Aug 2020 22:03'	System	22 Aug 2020 03:03:32
	System	22 Aug 2020 03:03:32

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 6'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9689cab3-b1b0-4f40-b47f-fb62b04a6a63' User entered 'None (1)'	System	23 Aug 2020 02:43:35
	System	23 Aug 2020 02:43:35

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9689cab3-b1b0-4f40-b47f-fb62b04a6a63' User entered 'No (N)'	System	23 Aug 2020 02:43:35
	System	23 Aug 2020 02:43:35

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:21', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9689cab3-b1b0-4f40-b47f-fb62b04a6a63' User entered 'No (N)'	System	23 Aug 2020 02:43:35
	System	23 Aug 2020 02:43:35

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9689cab3-b1b0-4f40-b47f-fb62b04a6a63' User entered 'None (1)'	System	23 Aug 2020 02:43:35
	System	23 Aug 2020 02:43:35

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:31', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9689cab3-b1b0-4f40-b47f-fb62b04a6a63' User entered '22 Aug 2020 21:43'	System	23 Aug 2020 02:43:35
	System	23 Aug 2020 02:43:35

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 7'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2c67f33e-7ef9-4e8f-b9c6-66a551867daa'	System	24 Aug 2020 01:57:37
User entered 'None (1)'	System	24 Aug 2020 01:57:37

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2c67f33e-7ef9-4e8f-b9c6-66a551867daa' User entered 'No (N)'	System	24 Aug 2020 01:57:37
	System	24 Aug 2020 01:57:37

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2c67f33e-7ef9-4e8f-b9c6-66a551867daa' User entered 'No (N)'	System	24 Aug 2020 01:57:37
	System	24 Aug 2020 01:57:37

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2c67f33e-7ef9-4e8f-b9c6-66a551867daa'	System	24 Aug 2020 01:57:37
User entered 'None (1)'	System	24 Aug 2020 01:57:37

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:34', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '2c67f33e-7ef9-4e8f-b9c6-66a551867daa' User entered '23 Aug 2020 20:57'	System	24 Aug 2020 01:57:37
	System	24 Aug 2020 01:57:37

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:51', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:26:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:27:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'None (0)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:27:12', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered 'No (N)'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T15:27:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7eaa8230-3372-4e0f-b080-1554e65e3ca3' User entered '17 Aug 2020 15:27'	System	17 Aug 2020 20:27:20
	System	17 Aug 2020 20:27:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 15:06'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 17:36'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:07', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfecb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfecb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfeeb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:19', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfeeb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfecb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfecb098423' User entered 'None (0)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:44', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfeeb098423' User entered 'No (N)'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-17T21:56:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c7a54051-b5c3-4800-a190-5cfecb098423' User entered '17 Aug 2020 21:56'	System	18 Aug 2020 02:56:52
	System	18 Aug 2020 02:56:52

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Aug 2020 18:31'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 2'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:30', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:33', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'None (0)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:34:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered 'No (N)'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-18T21:35:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21bbf63e-0ed6-4b99-a0a9-581910f19fc9' User entered '18 Aug 2020 21:35'	System	19 Aug 2020 02:35:20
	System	19 Aug 2020 02:35:20

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 3'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:51', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:06:55', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:07', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'None (0)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:28', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered 'No (N)'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-19T22:07:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd58ac800-c8ad-4cc9-b843-5f029a1ab70d' User entered '19 Aug 2020 22:07'	System	20 Aug 2020 03:07:56
	System	20 Aug 2020 03:07:56

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 4'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:16:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:03', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:13', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:16', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered 'None (0)'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506'	System	21 Aug 2020 02:17:31
User entered 'No (N)'	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-20T21:17:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7977a612-b205-4657-bc65-6413a8744506' User entered '20 Aug 2020 21:17'	System	21 Aug 2020 02:17:31
	System	21 Aug 2020 02:17:31

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 5'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:03:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:04:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:04:06', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'None (0)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:04:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered 'No (N)'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-21T22:04:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b1be64f1-1d21-49b2-92d0-4c1bb12928a9' User entered '21 Aug 2020 22:04'	System	22 Aug 2020 03:04:39
	System	22 Aug 2020 03:04:39

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 6'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:39', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:50', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'None (0)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:43:59', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered 'No (N)'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-22T21:44:02', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '37dc2377-765a-41b1-8c81-281f07faea5b' User entered '22 Aug 2020 21:44'	System	23 Aug 2020 02:44:04
	System	23 Aug 2020 02:44:04

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 7'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:56', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:57:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered 'None (0)'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:58:06', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009'	System	24 Aug 2020 01:58:21
User entered 'No (N)'	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-08-23T20:58:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b29d0923-36f0-4701-b0fb-c1bfaf181009' User entered '23 Aug 2020 20:58'	System	24 Aug 2020 01:58:21
	System	24 Aug 2020 01:58:21

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:18:02

US3862020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	26 Aug 2020 20:57:16

US3862020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '24 Aug 2020'	Sandra Francisco (b) (4)	26 Aug 2020 20:57:16

US3862020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4)	26 Aug 2020 20:57:16

US3862020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Sandra Francisco (b) (4)	26 Aug 2020 20:57:16

US3862020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	31 Aug 2020 22:01:21

US3862020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	31 Aug 2020 22:01:21

US3862020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	31 Aug 2020 22:01:51

US3862020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '31 Aug 2020'	Thea Marie Cordero (b) (4)	31 Aug 2020 22:01:51

US3862020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	31 Aug 2020 22:01:51

US3862020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Thea Marie Cordero (b) (4)	31 Aug 2020 22:01:51

US3862020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	31 Aug 2020 22:02:06

US3862020

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	31 Aug 2020 22:02:06

US3862020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:42:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Chanei Henry (b) (4)	08 Sep 2020 22:37:08
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	(b) (4)	04 Sep 2020 21:30:39
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:29:51
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:29:51
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	04 Sep 2020 21:29:51
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:29:43
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	04 Sep 2020 21:27:39

US3862020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '8 Sep 2020' reason for change: Data Entry Error	Chanei Henry (b) (4)	08 Sep 2020 22:37:08
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Sep 2020 21:29:43
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	04 Sep 2020 21:29:43
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	04 Sep 2020 21:29:43
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Sep 2020 21:27:39
User entered '4 Sep 2020'	Thea Marie Cordero (b) (4)	04 Sep 2020 21:27:39

US3862020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Chanei Henry (b) (4)	08 Sep 2020 22:37:08
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	04 Sep 2020 21:29:43
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	04 Sep 2020 21:27:39

US3862020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Thea Marie Cordero (b) (4)	04 Sep 2020 21:27:39

US3862020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Chanei Henry (b) (4)	08 Sep 2020 22:37:36
	(b) (4)	

US3862020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	08 Sep 2020 22:37:36

US3862020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 14:59:51
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Carrie Kibler (b) (4)	16 Sep 2020 14:59:51
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	16 Sep 2020 14:59:51
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'VISIT2'	System	16 Sep 2020 14:59:51

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '09:18'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Sep 2020 09:18'	System	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '98.8' F	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '75'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'bpm'	System	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '12'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'breaths/min'	System	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '128'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '65'	Carrie Kibler (b) (4)	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	16 Sep 2020 15:09:08

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Trent Davis (b) (4)	17 Sep 2020 16:08:47
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '11:14'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Sep 2020 11:14'	System	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '97.8' F	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Oral (Oral)'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '074'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'bpm'	System	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '016'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'breaths/min'	System	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '120'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '067'	Trent Davis (b) (4)	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	17 Sep 2020 16:08:47

US3862020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 15:00:42

US3862020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Carrie Kibler (b) (4)	16 Sep 2020 15:00:42
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '10:41'	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Sep 2020 10:41'	System	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Left Arm (LEFT ARM)'	Trent Davis (b) (4)	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'ONCE'	System	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:53:56

US3862020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:24

US3862020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:24
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '09:49'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:24
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Sep 2020 09:49'	System	16 Sep 2020 15:01:24

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Sep 2020'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:13
	(b) (4)	

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'No (N)'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Carrie Kibler (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered empty.	System	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '09:41'	Carrie Kibler (b) (4)	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Sep 2020 09:41'	System	16 Sep 2020 15:01:13

US3862020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Sep 2020 15:00:49

US3862020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	16 Sep 2020 15:00:49

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:15:50', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '60614a86-1ed0-45fc-b55f-49cefdcd91bf' User entered 'Yes (Y)'	System	16 Sep 2020 16:16:14
	System	16 Sep 2020 16:16:14

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:15:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '60614a86-1ed0-45fc-b55f-49cefdcd91bf' User entered '97.8'	System	16 Sep 2020 16:16:14
	System	16 Sep 2020 16:16:14

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:16:04', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '60614a86-1ed0-45fc-b55f-49cefdcd91bf' User entered 'No (N)'	System	16 Sep 2020 16:16:14
	System	16 Sep 2020 16:16:14

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:16:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '60614a86-1ed0-45fc-b55f-49cefdcd91bf' User entered '16 Sep 2020 11:16'	System	16 Sep 2020 16:16:14
	System	16 Sep 2020 16:16:14

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 11:01'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 13:31'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:30:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f04fdb76-ecc4-41fb-959b-5fcf801d0029' User entered 'Yes (Y)'	System	17 Sep 2020 05:31:12
	System	17 Sep 2020 05:31:12

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:30:52', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f04fdb76-ecc4-41fb-959b-5fcf801d0029' User entered '98.5'	System	17 Sep 2020 05:31:12
	System	17 Sep 2020 05:31:12

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:30:59', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f04fdb76-ecc4-41fb-959b-5fcf801d0029' User entered 'No (N)'	System	17 Sep 2020 05:31:12
	System	17 Sep 2020 05:31:12

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f04fdb76-ecc4-41fb-959b-5fcf801d0029' User entered '17 Sep 2020 00:31'	System	17 Sep 2020 05:31:12
	System	17 Sep 2020 05:31:12

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 14:26'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 2'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:44:39', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fe55164f-474e-4a8d-a992-fd2381f288bf' User entered 'Yes (Y)'	System	18 Sep 2020 02:45:15
	System	18 Sep 2020 02:45:15

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:44:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fe55164f-474e-4a8d-a992-fd2381f288bf' User entered '99.0'	System	18 Sep 2020 02:45:15
	System	18 Sep 2020 02:45:15

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fe55164f-474e-4a8d-a992-fd2381f288bf' User entered 'No (N)'	System	18 Sep 2020 02:45:15
	System	18 Sep 2020 02:45:15

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:13', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fe55164f-474e-4a8d-a992-fd2381f288bf' User entered '17 Sep 2020 21:45'	System	18 Sep 2020 02:45:15
	System	18 Sep 2020 02:45:15

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 3'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:54:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c247b38b-801d-4aa5-bfdb-03d40c310395' User entered 'Yes (Y)'	System	19 Sep 2020 01:54:48
	System	19 Sep 2020 01:54:48

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:54:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c247b38b-801d-4aa5-bfdb-03d40c310395' User entered '97.9'	System	19 Sep 2020 01:54:48
	System	19 Sep 2020 01:54:48

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:54:32', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c247b38b-801d-4aa5-bfdb-03d40c310395' User entered 'No (N)'	System	19 Sep 2020 01:54:48
	System	19 Sep 2020 01:54:48

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:54:45', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c247b38b-801d-4aa5-bfdb-03d40c310395' User entered '18 Sep 2020 20:54'	System	19 Sep 2020 01:54:48
	System	19 Sep 2020 01:54:48

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 4'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:54:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c54b7f0e-f63c-4072-a0c9-6d6d95082f45'	System	20 Sep 2020 01:55:27
User entered 'Yes (Y)'	System	20 Sep 2020 01:55:27

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c54b7f0e-f63c-4072-a0c9-6d6d95082f45' User entered '97.8'	System	20 Sep 2020 01:55:27
	System	20 Sep 2020 01:55:27

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c54b7f0e-f63c-4072-a0c9-6d6d95082f45'	System	20 Sep 2020 01:55:27
User entered 'No (N)'	System	20 Sep 2020 01:55:27

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'c54b7f0e-f63c-4072-a0c9-6d6d95082f45' User entered '19 Sep 2020 20:55'	System	20 Sep 2020 01:55:27
	System	20 Sep 2020 01:55:27

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 5'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8cee77d7-9eb9-4d5e-99aa-d566813842b3' User entered 'Yes (Y)'	System	21 Sep 2020 01:03:44
	System	21 Sep 2020 01:03:44

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:28', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8cee77d7-9eb9-4d5e-99aa-d566813842b3' User entered '98.9'	System	21 Sep 2020 01:03:44
	System	21 Sep 2020 01:03:44

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:34', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8cee77d7-9eb9-4d5e-99aa-d566813842b3' User entered 'No (N)'	System	21 Sep 2020 01:03:44
	System	21 Sep 2020 01:03:44

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8cee77d7-9eb9-4d5e-99aa-d566813842b3' User entered '20 Sep 2020 20:03'	System	21 Sep 2020 01:03:44
	System	21 Sep 2020 01:03:44

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 6'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '48299050-9ebe-4e82-b346-3b62a9c0dd28' User entered 'Yes (Y)'	System	22 Sep 2020 01:41:25
	System	22 Sep 2020 01:41:25

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '48299050-9ebe-4e82-b346-3b62a9c0dd28' User entered '98.6'	System	22 Sep 2020 01:41:25
	System	22 Sep 2020 01:41:25

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '48299050-9ebe-4e82-b346-3b62a9c0dd28' User entered 'No (N)'	System	22 Sep 2020 01:41:25
	System	22 Sep 2020 01:41:25

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '48299050-9ebe-4e82-b346-3b62a9c0dd28' User entered '21 Sep 2020 20:41'	System	22 Sep 2020 01:41:25
	System	22 Sep 2020 01:41:25

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 7'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5bd78265-497a-49e3-82fd-2545c3199788' User entered 'Yes (Y)'	System	22 Sep 2020 17:49:39
	System	22 Sep 2020 17:49:39

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5bd78265-497a-49e3-82fd-2545c3199788' User entered '98.3'	System	22 Sep 2020 17:49:39
	System	22 Sep 2020 17:49:39

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:28', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5bd78265-497a-49e3-82fd-2545c3199788' User entered 'No (N)'	System	22 Sep 2020 17:49:39
	System	22 Sep 2020 17:49:39

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:35', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5bd78265-497a-49e3-82fd-2545c3199788' User entered '22 Sep 2020 12:49'	System	22 Sep 2020 17:49:39
	System	22 Sep 2020 17:49:39

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:16:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fb3095fc-9240-47bf-9163-12c0f7f262de' User entered 'None (1)'	System	16 Sep 2020 16:18:29
	System	16 Sep 2020 16:18:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:17:35', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fb3095fc-9240-47bf-9163-12c0f7f262de' User entered 'No (N)'	System	16 Sep 2020 16:18:29
	System	16 Sep 2020 16:18:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:16', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fb3095fc-9240-47bf-9163-12c0f7f262de' User entered 'No (N)'	System	16 Sep 2020 16:18:29
	System	16 Sep 2020 16:18:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fb3095fc-9240-47bf-9163-12c0f7f262de' User entered 'None (1)'	System	16 Sep 2020 16:18:29
	System	16 Sep 2020 16:18:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'fb3095fc-9240-47bf-9163-12c0f7f262de' User entered '16 Sep 2020 11:18'	System	16 Sep 2020 16:18:29
	System	16 Sep 2020 16:18:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 11:01'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 13:31'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '0a80602a-d70c-4081-8ea8-2abac46c39bc' User entered 'None (1)'	System	17 Sep 2020 05:31:57
	System	17 Sep 2020 05:31:57

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '0a80602a-d70c-4081-8ea8-2abac46c39bc' User entered 'No (N)'	System	17 Sep 2020 05:31:57
	System	17 Sep 2020 05:31:57

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:38', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '0a80602a-d70c-4081-8ea8-2abac46c39bc' User entered 'No (N)'	System	17 Sep 2020 05:31:57
	System	17 Sep 2020 05:31:57

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '0a80602a-d70c-4081-8ea8-2abac46c39bc' User entered 'None (1)'	System	17 Sep 2020 05:31:57
	System	17 Sep 2020 05:31:57

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:31:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '0a80602a-d70c-4081-8ea8-2abac46c39bc' User entered '17 Sep 2020 00:31'	System	17 Sep 2020 05:31:57
	System	17 Sep 2020 05:31:57

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 14:26'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 2'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5d92dd57-97a1-451c-a739-bb2ed76e7c22'	System	18 Sep 2020 02:45:45
User entered 'None (1)'	System	18 Sep 2020 02:45:45

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5d92dd57-97a1-451c-a739-bb2ed76e7c22' User entered 'No (N)'	System	18 Sep 2020 02:45:45
	System	18 Sep 2020 02:45:45

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:33', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5d92dd57-97a1-451c-a739-bb2ed76e7c22'	System	18 Sep 2020 02:45:45
User entered 'No (N)'	System	18 Sep 2020 02:45:45

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:39', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5d92dd57-97a1-451c-a739-bb2ed76e7c22'	System	18 Sep 2020 02:45:45
User entered 'None (1)'	System	18 Sep 2020 02:45:45

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '5d92dd57-97a1-451c-a739-bb2ed76e7c22' User entered '17 Sep 2020 21:45'	System	18 Sep 2020 02:45:45
	System	18 Sep 2020 02:45:45

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 3'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:54:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a6289bce-cdec-409e-942b-c2f452d0c5f6' User entered 'None (1)'	System	19 Sep 2020 01:55:29
	System	19 Sep 2020 01:55:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a6289bce-cdec-409e-942b-c2f452d0c5f6' User entered 'No (N)'	System	19 Sep 2020 01:55:29
	System	19 Sep 2020 01:55:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a6289bce-cdec-409e-942b-c2f452d0c5f6' User entered 'No (N)'	System	19 Sep 2020 01:55:29
	System	19 Sep 2020 01:55:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:16', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a6289bce-cdec-409e-942b-c2f452d0c5f6' User entered 'None (1)'	System	19 Sep 2020 01:55:29
	System	19 Sep 2020 01:55:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a6289bce-cdec-409e-942b-c2f452d0c5f6' User entered '18 Sep 2020 20:55'	System	19 Sep 2020 01:55:29
	System	19 Sep 2020 01:55:29

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 4'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc08145a-c254-45da-b272-4856aa3fc9e4' User entered 'None (1)'	System	20 Sep 2020 01:56:11
	System	20 Sep 2020 01:56:11

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc08145a-c254-45da-b272-4856aa3fc9e4' User entered 'No (N)'	System	20 Sep 2020 01:56:11
	System	20 Sep 2020 01:56:11

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:51', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc08145a-c254-45da-b272-4856aa3fc9e4' User entered 'No (N)'	System	20 Sep 2020 01:56:11
	System	20 Sep 2020 01:56:11

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:55:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc08145a-c254-45da-b272-4856aa3fc9e4' User entered 'None (1)'	System	20 Sep 2020 01:56:11
	System	20 Sep 2020 01:56:11

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:56:10', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'cc08145a-c254-45da-b272-4856aa3fc9e4' User entered '19 Sep 2020 20:56'	System	20 Sep 2020 01:56:11
	System	20 Sep 2020 01:56:11

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 5'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:48', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '80e79eba-09e8-4bab-9d36-72eecf9cf2d8'	System	21 Sep 2020 01:04:09
User entered 'None (1)'	System	21 Sep 2020 01:04:09

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '80e79eba-09e8-4bab-9d36-72eecf9cf2d8' User entered 'No (N)'	System	21 Sep 2020 01:04:09
	System	21 Sep 2020 01:04:09

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:03:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '80e79eba-09e8-4bab-9d36-72eecf9cf2d8' User entered 'No (N)'	System	21 Sep 2020 01:04:09
	System	21 Sep 2020 01:04:09

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:02', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '80e79eba-09e8-4bab-9d36-72eecf9cf2d8'	System	21 Sep 2020 01:04:09
User entered 'None (1)'	System	21 Sep 2020 01:04:09

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '80e79eba-09e8-4bab-9d36-72eecf9cf2d8' User entered '20 Sep 2020 20:04'	System	21 Sep 2020 01:04:09
	System	21 Sep 2020 01:04:09

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 6'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:32', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f40be9b2-7aed-4bff-b541-bc02bcb680cd' User entered 'None (1)'	System	22 Sep 2020 01:41:50
	System	22 Sep 2020 01:41:50

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f40be9b2-7aed-4bff-b541-bc02bcb680cd' User entered 'No (N)'	System	22 Sep 2020 01:41:50
	System	22 Sep 2020 01:41:50

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f40be9b2-7aed-4bff-b541-bc02bcb680cd' User entered 'No (N)'	System	22 Sep 2020 01:41:50
	System	22 Sep 2020 01:41:50

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:45', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f40be9b2-7aed-4bff-b541-bc02bcb680cd' User entered 'None (1)'	System	22 Sep 2020 01:41:50
	System	22 Sep 2020 01:41:50

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:48', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'f40be9b2-7aed-4bff-b541-bc02bcb680cd' User entered '21 Sep 2020 20:41'	System	22 Sep 2020 01:41:50
	System	22 Sep 2020 01:41:50

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 7'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd21f4f07-62c8-4c94-94a0-3f4761cee6f1' User entered 'None (1)'	System	22 Sep 2020 17:49:59
	System	22 Sep 2020 17:49:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd21f4f07-62c8-4c94-94a0-3f4761cee6f1' User entered 'No (N)'	System	22 Sep 2020 17:49:59
	System	22 Sep 2020 17:49:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd21f4f07-62c8-4c94-94a0-3f4761cee6f1' User entered 'No (N)'	System	22 Sep 2020 17:49:59
	System	22 Sep 2020 17:49:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd21f4f07-62c8-4c94-94a0-3f4761cee6f1' User entered 'None (1)'	System	22 Sep 2020 17:49:59
	System	22 Sep 2020 17:49:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:49:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd21f4f07-62c8-4c94-94a0-3f4761cee6f1' User entered '22 Sep 2020 12:49'	System	22 Sep 2020 17:49:59
	System	22 Sep 2020 17:49:59

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:44', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:48', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:55', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:18:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:19:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'None (0)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:19:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered 'No (N)'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-16T11:19:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd8594b82-3d83-4dee-8203-860fafa4f2ae' User entered '16 Sep 2020 11:19'	System	16 Sep 2020 16:19:14
	System	16 Sep 2020 16:19:14

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 11:01'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 13:31'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:02', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:05', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:12', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'None (0)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered 'No (N)'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T00:32:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '00a05f48-4fc3-4aae-bacb-af487ff4aca0' User entered '17 Sep 2020 00:32'	System	17 Sep 2020 05:32:38
	System	17 Sep 2020 05:32:38

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '16 Sep 2020 14:26'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 2'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:45:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:04', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:08', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:10', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55' User entered 'None (0)'	System	18 Sep 2020 02:46:25
	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55'	System	18 Sep 2020 02:46:25
User entered 'No (N)'	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-17T21:46:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c662f9f-ce1c-4710-ba0e-e4c7c27c5d55'	System	18 Sep 2020 02:46:25
User entered '17 Sep 2020 21:46'	System	18 Sep 2020 02:46:25

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 3'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:39', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'None (0)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:55:59', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered 'No (N)'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-18T20:56:12', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '168d91bf-532b-4fd0-843a-9373722f1ea6' User entered '18 Sep 2020 20:56'	System	19 Sep 2020 01:56:16
	System	19 Sep 2020 01:56:16

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 4'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:56:31', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'No interference with activity (1)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:56:44', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd'	System	20 Sep 2020 01:57:42
User entered 'Some interference with activity (2)'	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:56:50', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'None (0)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:57:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'No interference with activity (1)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:57:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'None (0)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:57:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'None (0)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:57:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered 'No (N)'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-19T20:57:41', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '77055bbe-cb6a-444f-b546-7430b5aa35cd' User entered '19 Sep 2020 20:57'	System	20 Sep 2020 01:57:42
	System	20 Sep 2020 01:57:42

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 5'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:13', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'None (0)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee'	System	21 Sep 2020 01:04:57
User entered 'No interference with activity (1)'	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:33', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'None (0)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'None (0)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:43', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'None (0)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'None (0)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:52', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered 'No (N)'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-20T20:04:55', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'd944e56a-b099-44f1-8d69-30b770e275ee' User entered '20 Sep 2020 20:04'	System	21 Sep 2020 01:04:57
	System	21 Sep 2020 01:04:57

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 6'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:41:57', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:03', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:06', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'None (0)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered 'No (N)'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-21T20:42:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'ac729121-9a5f-4890-8bbb-4063f511693b' User entered '21 Sep 2020 20:42'	System	22 Sep 2020 01:42:18
	System	22 Sep 2020 01:42:18

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	16 Sep 2020 15:53:56
User entered 'Day 7'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:03', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:06', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:12', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'None (0)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

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 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered 'No (N)'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-09-22T12:50:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'b12bd497-731c-4be3-bd79-217bb5b05458' User entered '22 Sep 2020 12:50'	System	22 Sep 2020 17:50:28
	System	22 Sep 2020 17:50:28

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:53:56

US3862020

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:59:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:53:56

US3862020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	23 Sep 2020 17:55:53

US3862020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '23 Sep 2020'	Thea Marie Cordero (b) (4)	23 Sep 2020 17:55:53

US3862020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	23 Sep 2020 17:55:53

US3862020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Thea Marie Cordero (b) (4)	23 Sep 2020 17:55:53

US3862020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	23 Sep 2020 17:56:01

US3862020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	23 Sep 2020 17:56:01

US3862020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Chanei Henry (b) (4)	30 Sep 2020 23:53:50

US3862020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '30 Sep 2020'	Chanei Henry (b) (4)	30 Sep 2020 23:53:50
	(b) (4)	

US3862020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	30 Sep 2020 23:53:50

US3862020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Chanei Henry (b) (4)	30 Sep 2020 23:53:50
	(b) (4)	

US3862020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Chanei Henry (b) (4)	30 Sep 2020 23:53:55

US3862020

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	30 Sep 2020 23:53:55

US3862020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	08 Oct 2020 13:40:38

US3862020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '8 Oct 2020'	Thea Marie Cordero (b) (4)	08 Oct 2020 13:40:38

US3862020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	08 Oct 2020 13:40:38

US3862020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered empty.	Thea Marie Cordero (b) (4)	08 Oct 2020 13:40:38

US3862020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	08 Oct 2020 13:40:44

US3862020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	08 Oct 2020 13:40:44

US3862020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 21:07:43

US3862020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '16 Oct 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:27:33
User entered '12 Oct 2020'	Shetel Anassi (b) (4)	12 Oct 2020 21:07:43

US3862020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Clinic (Clinic)'	Shetel Anassi (b) (4)	12 Oct 2020 21:07:43
	(b) (4)	

US3862020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'VISIT3'	System	12 Oct 2020 21:07:43

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:28:29
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 15:28:29
User entered '16 Oct 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:27:33
User entered '12 Oct 2020'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '09:02' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '12:23'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Oct 2020 09:02'	System	19 Oct 2020 15:28:29
User entered '12 Oct 2020 12:23'	System	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '097.9' F reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '097.7' F	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Other (Other)'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47
	(b) (4)	

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Temporal'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '076' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '077'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'bpm'	System	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '018' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '016'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'breaths/min'	System	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '110' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '144'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '063' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:28:29
User entered '067'	Shetel Anassi (b) (4)	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'mmHg'	System	12 Oct 2020 21:08:47

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59

US3862020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59

US3862020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	16 Oct 2020 15:03:23
User entered 'No (N)'	Shetel Anassi (b) (4)	12 Oct 2020 21:10:03

US3862020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:27:33
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Oct 2020 15:03:23
User entered '16 Oct 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	16 Oct 2020 15:03:23
User entered empty.	Shetel Anassi (b) (4)	12 Oct 2020 21:10:03

US3862020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 21:10:49

US3862020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:27:33
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		19 Oct 2020 15:27:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:27:07
User entered '16 Oct 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:27:07
User entered '12 Oct 2020'	Shetel Anassi (b) (4)	12 Oct 2020 21:10:49

US3862020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered '09:40' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:29:00
User entered '09:02' reason for change: Data Entry Error	Shetel Anassi (b) (4)	19 Oct 2020 15:27:07
User entered '12:50'	Shetel Anassi (b) (4)	12 Oct 2020 21:10:49

US3862020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered '16 Oct 2020 09:40'	System	19 Oct 2020 15:29:00
User entered '16 Oct 2020 09:02'	System	19 Oct 2020 15:27:07
User entered '12 Oct 2020 12:50'	System	12 Oct 2020 21:10:49

US3862020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:46
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Oct 2020 21:10:55

US3862020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	12 Oct 2020 21:10:55

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 64'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-20T18:17:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '376b2faf-b9c2-4c52-a510-126052bb31e3' User entered 'No (N)'	System	20 Oct 2020 23:18:44
	System	20 Oct 2020 23:18:44

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-20T18:17:25', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '376b2faf-b9c2-4c52-a510-126052bb31e3' User entered 'No (N)'	System	20 Oct 2020 23:18:44
	System	20 Oct 2020 23:18:44

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-20T18:17:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '376b2faf-b9c2-4c52-a510-126052bb31e3' User entered '20 Oct 2020 18:17:42'	System	20 Oct 2020 23:18:44
	System	20 Oct 2020 23:18:44

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 71'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-24T00:01:41', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '85efaca3-5b19-4273-befd-2e26266cf38b' User entered 'No (N)'	System	24 Oct 2020 05:02:08
	System	24 Oct 2020 05:02:08

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-24T00:01:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '85efaca3-5b19-4273-befd-2e26266cf38b'	System	24 Oct 2020 05:02:08
User entered 'No (N)'	System	24 Oct 2020 05:02:08

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-24T00:02:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '85efaca3-5b19-4273-befd-2e26266cf38b' User entered '24 Oct 2020 00:02:01'	System	24 Oct 2020 05:02:08
	System	24 Oct 2020 05:02:08

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 78'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-31T00:01:31', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c7097d9-757b-457d-94aa-fce4700a5832' User entered 'No (N)'	System	31 Oct 2020 05:01:55
	System	31 Oct 2020 05:01:55

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-31T00:01:41', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c7097d9-757b-457d-94aa-fce4700a5832'	System	31 Oct 2020 05:01:55
User entered 'No (N)'	System	31 Oct 2020 05:01:55

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-10-31T00:01:49', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '8c7097d9-757b-457d-94aa-fce4700a5832' User entered '31 Oct 2020 00:01:49'	System	31 Oct 2020 05:01:55
	System	31 Oct 2020 05:01:55

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered 'Day 92'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-14T00:01:56', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '276fe227-59bb-4d2d-ab28-4120ea9a45d1' User entered 'No (N)'	System	14 Nov 2020 06:02:27
	System	14 Nov 2020 06:02:27

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-14T00:02:15', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '276fe227-59bb-4d2d-ab28-4120ea9a45d1' User entered 'No (N)'	System	14 Nov 2020 06:02:27
	System	14 Nov 2020 06:02:27

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-14T00:02:24', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '276fe227-59bb-4d2d-ab28-4120ea9a45d1' User entered '14 Nov 2020 00:02:24'	System	14 Nov 2020 06:02:27
	System	14 Nov 2020 06:02:27

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:18:02

US3862020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:50:18
Data entry locked.	System	17 Aug 2020 20:18:02
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:18:02

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-25T00:01:59', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21480c88-4e1b-4ee1-920a-f23fccd0a1c6'	System	25 Nov 2020 06:03:25
User entered 'No (N)'	System	25 Nov 2020 06:03:25

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-25T00:03:11', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21480c88-4e1b-4ee1-920a-f23fccd0a1c6'	System	25 Nov 2020 06:03:25
User entered 'No (N)'	System	25 Nov 2020 06:03:25

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-11-25T00:03:19', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '21480c88-4e1b-4ee1-920a-f23fccd0a1c6'	System	25 Nov 2020 06:03:25
User entered '25 Nov 2020 00:03:19'	System	25 Nov 2020 06:03:25

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-02T14:31:14', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '90991a1d-931a-4539-afc5-bcdeee46c465' User entered 'No (N)'	System	02 Dec 2020 20:32:05
	System	02 Dec 2020 20:32:05

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-02T14:31:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '90991a1d-931a-4539-afc5-bcdeee46c465'	System	02 Dec 2020 20:32:05
User entered 'No (N)'	System	02 Dec 2020 20:32:05

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-02T14:32:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '90991a1d-931a-4539-afc5-bcdeee46c465' User entered '02 Dec 2020 14:32:00'	System	02 Dec 2020 20:32:05
	System	02 Dec 2020 20:32:05

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-09T21:05:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bec9845a-bd3b-403a-af06-e0fc72a3091e' User entered 'No (N)'	System	10 Dec 2020 03:05:48
	System	10 Dec 2020 03:05:48

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-09T21:05:40', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bec9845a-bd3b-403a-af06-e0fc72a3091e' User entered 'No (N)'	System	10 Dec 2020 03:05:48
	System	10 Dec 2020 03:05:48

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-09T21:05:45', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'bec9845a-bd3b-403a-af06-e0fc72a3091e' User entered '09 Dec 2020 21:05:45'	System	10 Dec 2020 03:05:48
	System	10 Dec 2020 03:05:48

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-19T23:30:36', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7e7a1cd6-bafc-4c2a-9e59-406afc1a59e4' User entered 'No (N)'	System	20 Dec 2020 05:30:56
	System	20 Dec 2020 05:30:56

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-19T23:30:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7e7a1cd6-bafc-4c2a-9e59-406afc1a59e4' User entered 'No (N)'	System	20 Dec 2020 05:30:56
	System	20 Dec 2020 05:30:56

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-19T23:30:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '7e7a1cd6-bafc-4c2a-9e59-406afc1a59e4' User entered '19 Dec 2020 23:30:53'	System	20 Dec 2020 05:30:56
	System	20 Dec 2020 05:30:56

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-23T00:01:29', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '6a57700f-2378-4af4-8d22-b9d302ce9e40' User entered 'No (N)'	System	23 Dec 2020 06:03:43
	System	23 Dec 2020 06:03:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-23T00:01:38', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '6a57700f-2378-4af4-8d22-b9d302ce9e40' User entered 'Yes (Y)'	System	23 Dec 2020 06:03:43
	System	23 Dec 2020 06:03:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Please 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-23T00:02:22', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '6a57700f-2378-4af4-8d22-b9d302ce9e40'	System	23 Dec 2020 06:03:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 06:03:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-23T00:03:31', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '6a57700f-2378-4af4-8d22-b9d302ce9e40' User entered '23 Dec 2020 00:03:31'	System	23 Dec 2020 06:03:43
	System	23 Dec 2020 06:03:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-31T18:40:07', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a7039e01-2fd5-4287-b2d4-5a383d1243b0'	System	01 Jan 2021 00:40:27
User entered 'No (N)'	System	01 Jan 2021 00:40:27

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-31T18:40:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a7039e01-2fd5-4287-b2d4-5a383d1243b0'	System	01 Jan 2021 00:40:27
User entered 'No (N)'	System	01 Jan 2021 00:40:27

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2020-12-31T18:40:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a7039e01-2fd5-4287-b2d4-5a383d1243b0' User entered '31 Dec 2020 18:40:23'	System	01 Jan 2021 00:40:27
	System	01 Jan 2021 00:40:27

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-06T08:56:26', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1153feb6-4c26-43bd-b076-8af772c21915'	System	06 Jan 2021 14:57:11
User entered 'Yes (Y)'	System	06 Jan 2021 14:57:11

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-06T08:56:34', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1153feb6-4c26-43bd-b076-8af772c21915'	System	06 Jan 2021 14:57:11
User entered 'No (N)'	System	06 Jan 2021 14:57:11

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-06T08:56:42', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1153feb6-4c26-43bd-b076-8af772c21915'	System	06 Jan 2021 14:57:11
User entered 'No (N)'	System	06 Jan 2021 14:57:11

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-06T08:56:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1153feb6-4c26-43bd-b076-8af772c21915' User entered 'No (N)'	System	06 Jan 2021 14:57:11
	System	06 Jan 2021 14:57:11

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-06T08:57:09', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1153feb6-4c26-43bd-b076-8af772c21915'	System	06 Jan 2021 14:57:11
User entered '06 Jan 2021 08:57:09'	System	06 Jan 2021 14:57:11

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-13T14:30:10', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b87ea3f-d6da-4f01-bd37-8c0e205c43a1' User entered 'Yes (Y)'	System	13 Jan 2021 20:31:10
	System	13 Jan 2021 20:31:10

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-13T14:30:20', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b87ea3f-d6da-4f01-bd37-8c0e205c43a1' User entered 'No (N)'	System	13 Jan 2021 20:31:10

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-13T14:30:27', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b87ea3f-d6da-4f01-bd37-8c0e205c43a1'	System	13 Jan 2021 20:31:10
User entered 'No (N)'	System	13 Jan 2021 20:31:10

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-13T14:30:37', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b87ea3f-d6da-4f01-bd37-8c0e205c43a1' User entered 'No (N)'	System	13 Jan 2021 20:31:10
	System	13 Jan 2021 20:31:10

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-13T14:30:54', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b87ea3f-d6da-4f01-bd37-8c0e205c43a1' User entered '13 Jan 2021 14:30:54'	System	13 Jan 2021 20:31:10
	System	13 Jan 2021 20:31:10

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-21T14:31:47', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4c55e4fe-a4ef-42fd-9e78-69def101d7c4'	System	21 Jan 2021 20:32:06
User entered 'No (N)'	System	21 Jan 2021 20:32:06

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-21T14:31:58', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4c55e4fe-a4ef-42fd-9e78-69def101d7c4'	System	21 Jan 2021 20:32:06
User entered 'No (N)'	System	21 Jan 2021 20:32:06

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-21T14:32:02', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4c55e4fe-a4ef-42fd-9e78-69def101d7c4'	System	21 Jan 2021 20:32:06
User entered '21 Jan 2021 14:32:02'	System	21 Jan 2021 20:32:06

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-30T18:04:10', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '152e3479-d5b6-4878-89e9-b5041d80ab83'	System	31 Jan 2021 00:04:43
User entered 'No (N)'	System	31 Jan 2021 00:04:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-30T18:04:17', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '152e3479-d5b6-4878-89e9-b5041d80ab83'	System	31 Jan 2021 00:04:43
User entered 'No (N)'	System	31 Jan 2021 00:04:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-01-30T18:04:23', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '152e3479-d5b6-4878-89e9-b5041d80ab83' User entered '30 Jan 2021 18:04:23'	System	31 Jan 2021 00:04:43
	System	31 Jan 2021 00:04:43

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-03T09:01:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b205bc8-2285-4625-92e3-0700502265ac'	System	03 Feb 2021 15:02:23
User entered 'No (N)'	System	03 Feb 2021 15:02:23

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-03T09:02:01', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b205bc8-2285-4625-92e3-0700502265ac'	System	03 Feb 2021 15:02:23
User entered 'No (N)'	System	03 Feb 2021 15:02:23

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-03T09:02:18', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1b205bc8-2285-4625-92e3-0700502265ac'	System	03 Feb 2021 15:02:23
User entered '03 Feb 2021 09:02:18'	System	03 Feb 2021 15:02:23

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-12T12:54:31', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'df0ea077-d099-41a7-a4db-00af58196b9e' User entered 'No (N)'	System	12 Feb 2021 18:54:57
	System	12 Feb 2021 18:54:57

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-12T12:54:46', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'df0ea077-d099-41a7-a4db-00af58196b9e' User entered 'No (N)'	System	12 Feb 2021 18:54:57
	System	12 Feb 2021 18:54:57

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (113293F9-5552-40BA-8009-5F06C075E700)', Time: '2021-02-12T12:54:53', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'df0ea077-d099-41a7-a4db-00af58196b9e' User entered '12 Feb 2021 12:54:53'	System	12 Feb 2021 18:54:57
	System	12 Feb 2021 18:54:57

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-03-31T10:30:17-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a124ab7-2648-426c-8c4e-9b7ac2fc46f5'	System	31 Mar 2021 15:30:35
User entered 'No (N)'	System	31 Mar 2021 15:30:35

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you been exposed to someone with 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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-03-31T10:30:24-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a124ab7-2648-426c-8c4e-9b7ac2fc46f5'	System	31 Mar 2021 15:30:35
User entered 'No (N)'	System	31 Mar 2021 15:30:35

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-03-31T10:30:32-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '1a124ab7-2648-426c-8c4e-9b7ac2fc46f5'	System	31 Mar 2021 15:30:35
User entered '31 Mar 2021 10:30:32'	System	31 Mar 2021 15:30:35

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-09T12:06:34-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4f81311f-690a-4218-9ca6-e32707a26083'	System	09 Apr 2021 17:09:07
User entered 'No (N)'	System	09 Apr 2021 17:09:07

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you been exposed to someone with 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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-09T12:06:40-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4f81311f-690a-4218-9ca6-e32707a26083'	System	09 Apr 2021 17:09:07
User entered 'No (N)'	System	09 Apr 2021 17:09:07

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-09T12:06:46-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '4f81311f-690a-4218-9ca6-e32707a26083'	System	09 Apr 2021 17:09:07
User entered '09 Apr 2021 12:06:46'	System	09 Apr 2021 17:09:07

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-14T11:35:21-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '213126e1-3c52-4a5b-9e25-12b698dac522'	System	14 Apr 2021 16:35:42
User entered 'No (N)'	System	14 Apr 2021 16:35:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-14T11:35:32-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '213126e1-3c52-4a5b-9e25-12b698dac522'	System	14 Apr 2021 16:35:42
User entered 'No (N)'	System	14 Apr 2021 16:35:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-14T11:35:37-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '213126e1-3c52-4a5b-9e25-12b698dac522'	System	14 Apr 2021 16:35:42
User entered '14 Apr 2021 11:35:37'	System	14 Apr 2021 16:35:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-23T21:26:34-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9c411400-bc03-4862-8689-b4bc0c3d90cb' User entered 'No (N)'	System	24 Apr 2021 02:31:42
	System	24 Apr 2021 02:31:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Have you been exposed to someone with 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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-23T21:26:39-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9c411400-bc03-4862-8689-b4bc0c3d90cb' User entered 'No (N)'	System	24 Apr 2021 02:31:42
	System	24 Apr 2021 02:31:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-23T21:26:43-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: '9c411400-bc03-4862-8689-b4bc0c3d90cb' User entered '23 Apr 2021 21:26:43'	System	24 Apr 2021 02:31:42
	System	24 Apr 2021 02:31:42

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-28T17:37:33-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a71758f4-5b5d-480f-ab3e-3af1eac45b81' User entered 'No (N)'	System	28 Apr 2021 22:39:54
	System	28 Apr 2021 22:39:54

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

Have you been exposed to someone with 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 (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-28T17:37:41-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a71758f4-5b5d-480f-ab3e-3af1eac45b81'	System	28 Apr 2021 22:39:54
User entered 'No (N)'	System	28 Apr 2021 22:39:54

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-04-28T17:37:52-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a71758f4-5b5d-480f-ab3e-3af1eac45b81'	System	28 Apr 2021 22:39:54
User entered '28 Apr 2021 17:37:52'	System	28 Apr 2021 22:39:54

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:28:30

US3862020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:28:30
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:28:30

US3862020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:43

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 20:21:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-03-29T10:41:24-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a135f01b-8749-415b-a93a-12647c78286b'	System	29 Mar 2021 15:41:45
User entered 'No (N)'	System	29 Mar 2021 15:41:45

US3862020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:21:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5ADBC18C-649C-4EF8-8F00-35F88A23C437)', Time: '2021-03-29T10:41:41-05:00', User OID: 'PatientReportedOutcome (US3862020)', ODM File OID: 'a135f01b-8749-415b-a93a-12647c78286b' User entered '29 Mar 2021 10:41:41'	System	29 Mar 2021 15:41:45
	System	29 Mar 2021 15:41:45

US3862020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:13
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	13 Nov 2020 23:53:42

US3862020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:13
User entered '13 Nov 2020'	Thea Marie Cordero (b) (4)	13 Nov 2020 23:53:42

US3862020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:13
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	13 Nov 2020 23:53:42

US3862020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:13
User entered empty.	Thea Marie Cordero (b) (4)	13 Nov 2020 23:53:42

US3862020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:13
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	13 Nov 2020 23:53:47

US3862020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:42:59
User entered 'I'	System	13 Nov 2020 23:53:47

US3862020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	15 Dec 2020 22:42:29

US3862020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '15 Dec 2020'	Thea Marie Cordero (b) (4)	15 Dec 2020 22:42:29

US3862020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	15 Dec 2020 22:42:29

US3862020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 22:42:29

US3862020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	15 Dec 2020 22:42:35

US3862020

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'I'	System	15 Dec 2020 22:42:35

US3862020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:39:30

US3862020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 13:00:17
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Safety call completed outside of window. PD filed in source' (Site from System).	Sandra Francisco (b) (4)	21 Jan 2021 19:38:43
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	20 Jan 2021 20:39:30
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:39:30

US3862020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:39:30

US3862020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 20:39:30

US3862020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:40:20

US3862020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'I'	System	20 Jan 2021 20:40:20

US3862020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Mar 2021 22:44:34

US3862020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	03 Mar 2021 22:44:34

US3862020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	03 Mar 2021 22:44:34

US3862020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	03 Mar 2021 22:44:34
	(b) (4)	

US3862020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Mar 2021 22:44:37

US3862020

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'I'	System	03 Mar 2021 22:44:37

US3862020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Mar 2021 22:44:54

US3862020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '02 Mar 2021'	Carrie Kibler (b) (4)	03 Mar 2021 22:44:54
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	03 Mar 2021 22:44:54

US3862020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'VISIT4'	System	03 Mar 2021 22:44:54

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '02 Mar 2021'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '12:06'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered '02 Mar 2021 12:06'	System	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '97.9' F	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Other (Other)'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'temporal'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '104'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'bpm'	System	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '12'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'breaths/min'	System	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '100'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'mmHg'	System	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '60'	Carrie Kibler (b) (4)	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'mmHg'	System	30 Mar 2021 21:52:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31

US3862020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31

US3862020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Mar 2021 22:45:05

US3862020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '02 Mar 2021'	Carrie Kibler (b) (4)	03 Mar 2021 22:45:05
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Mar 2021 22:45:15

US3862020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	03 Mar 2021 22:45:15
	(b) (4)	

US3862020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	03 Mar 2021 22:45:15

US3862020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered empty.	System	03 Mar 2021 22:45:15

US3862020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Mar 2021 22:45:19

US3862020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:52:31
User entered 'I'	System	03 Mar 2021 22:45:19

US3862020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:15:34

US3862020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:15:34

US3862020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:15:34

US3862020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:15:34

US3862020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:15:40

US3862020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:15:40

US3862020

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:16
	(b) (4)	

US3862020

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:16
	(b) (4)	

US3862020

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Clinic (Clinic)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:16
	(b) (4)	

US3862020

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

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 21:12:16

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '0'	Carrie Kibler (b) (4)	22 Mar 2021 22:44:33
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:22:23

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Amendment 6 or later (Amendment 6 or later)'	Carrie Kibler (b) (4)	22 Mar 2021 22:44:33
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:22:23

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Placebo (Placebo)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Placebo (Placebo)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Placebo (Placebo)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:12:32
	(b) (4)	

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'I'	System	02 Mar 2021 21:12:32

US3862020

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

Form: Unblinding

Generated On: 10 Jun 2021 09:59:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'I'	System	02 Mar 2021 21:12:32

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	02 Mar 2021 21:14:16
DataPoint set to visible.	System	02 Mar 2021 21:12:32

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	02 Mar 2021 21:14:16
DataPoint set to visible.	System	02 Mar 2021 21:12:32

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User accepted default value 'Pre-Dose (PREDOSE)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '12:06'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2 Mar 2021 12:06'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '097.9' F	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Other (Other)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'temporal'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '104'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'bpm'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '012'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'breaths/min'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '100'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '060'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered missing code ND - Not Done.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	02 Mar 2021 21:14:16
DataPoint set to visible.	System	02 Mar 2021 21:12:32

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User accepted default value 'Post-Dose (POSTDOSE)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '14:15'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2 Mar 2021 14:15'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '097.5' F	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Other (Other)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'temporal'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '100'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'bpm'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '015'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'breaths/min'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '106'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '069'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:16
	(b) (4)	

US3862020

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mmHg'	System	02 Mar 2021 21:14:16

US3862020

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:23
	(b) (4)	

US3862020

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:23
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'mRNA-1273'	System	02 Mar 2021 21:14:38
DataPoint set to visible.	System	02 Mar 2021 21:12:32

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '13:40'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2 Mar 2021 13:40'	System	02 Mar 2021 21:14:38

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Right Arm (RIGHT ARM)'	Shetel Anassi (b) (4)	02 Mar 2021 21:14:38
	(b) (4)	

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'ONCE'	System	02 Mar 2021 21:14:38

US3862020

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

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 21:14:38

US3862020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'No (N)'	Shetel Anassi (b) (4)	02 Mar 2021 21:15:16
	(b) (4)	

US3862020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Shetel Anassi (b) (4)	02 Mar 2021 21:15:16
	(b) (4)	

US3862020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Shetel Anassi (b) (4)	02 Mar 2021 21:15:16
	(b) (4)	

US3862020

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered empty.	System	02 Mar 2021 21:15:16

US3862020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:15:28
	(b) (4)	

US3862020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '2 Mar 2021'	Shetel Anassi (b) (4)	02 Mar 2021 21:15:28
	(b) (4)	

US3862020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '12:30'	Shetel Anassi (b) (4)	02 Mar 2021 21:15:28
	(b) (4)	

US3862020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '2 Mar 2021 12:30'	System	02 Mar 2021 21:15:28

US3862020

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

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	02 Mar 2021 21:15:34
	(b) (4)	

US3862020

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

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:42:42
User entered '1'	System	02 Mar 2021 21:15:34

US3862020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 23:28:55

US3862020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 23:28:55

US3862020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 23:28:55

US3862020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 23:28:55

US3862020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 23:29:06

US3862020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User entered 'I'	System	09 Mar 2021 23:29:06

US3862020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:35:38
User entered '1'	System	09 Mar 2021 23:29:06
DataPoint set to visible.	System	09 Mar 2021 23:29:06

US3862020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Mar 2021 17:21:47
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '31 Mar 2021'	Carrie Kibler (b) (4)	31 Mar 2021 17:21:47
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	31 Mar 2021 17:21:47
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:43

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	31 Mar 2021 17:21:47

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shetel Anassi (b) (4) (b) (4)	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '31 Mar 2021'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '11:30'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 11:30'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '098.4' F	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Other (Other)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Temporal'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '099'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '015'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '108'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 04:11:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 20:14:50
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		31 Mar 2021 20:05:24
User entered '051'	Shetel Anassi (b) (4) (b) (4)	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shetel Anassi (b) (4) (b) (4)	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '31 Mar 2021'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '13:30'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 13:30'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '097.8' F	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Other (Other)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Temporal'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '104'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '015'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '109'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '060'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:24
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:05:24

US3862020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Mar 2021 17:21:52
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '31 Mar 2021'	Carrie Kibler (b) (4)	31 Mar 2021 17:21:52
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered empty.	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	31 Mar 2021 20:05:45
DataPoint set to visible.	System	09 Mar 2021 23:29:06

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '31 Mar 2021'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered '13:00'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 13:00'	System	31 Mar 2021 20:05:45

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:45
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	31 Mar 2021 20:05:45

US3862020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Mar 2021 20:05:45

US3862020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	31 Mar 2021 20:05:51
	(b) (4)	

US3862020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 20:05:51

US3862020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	07 Apr 2021 22:14:34
	(b) (4)	

US3862020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
	(b) (4)	
User entered '07 Apr 2021'	Thea Marie Cordero	07 Apr 2021 22:14:34
	(b) (4)	

US3862020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	07 Apr 2021 22:14:34
	(b) (4)	

US3862020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Apr 2021 22:14:34
	(b) (4)	

US3862020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	07 Apr 2021 22:15:30
	(b) (4)	

US3862020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 22:15:30

US3862020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:59:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:51
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:19
User entered 'Yes (Y)'	Chanei Henry (b) (4)	08 Sep 2020 22:37:47

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:03:18
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'NO. COUGH LASTED FOR 1 DAY' (Site from DM).	Thea Marie Cordero (b) (4)	18 Nov 2020 15:06:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:23:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:43:02
Data point term sent to Coder	System	08 Sep 2020 22:41:59
User entered 'Cough'	Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:18:32
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Updated' (Site from DM).	Thea Marie Cordero (b) (4)	28 Oct 2020 18:54:21
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	28 Oct 2020 18:54:04
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:00:15
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '07 Sep 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	18 Mar 2021 23:16:50
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	17 Sep 2020 00:00:23
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 15:53:56
User entered '7 Sep 2020'	Chanei Henry (b) (4)	08 Sep 2020 22:41:40
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User entered empty.	System	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	18 Mar 2021 23:16:50
User entered '7 Sep 2020'	(b) (4)	
	Chanei Henry (b) (4)	08 Sep 2020 22:41:40
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User entered empty.	System	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	Chanei Henry (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	Chanei Henry (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	Chanei Henry (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Sep 2020 20:23:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 20:23:18
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Chanei Henry (b) (4)	21 Sep 2020 20:23:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 22:41:40
User entered empty.	System	08 Sep 2020 22:41:40
	Chanei Henry (b) (4)	08 Sep 2020 22:41:40
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Sep 2020 20:23:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 20:23:18
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Chanei Henry (b) (4)	21 Sep 2020 20:23:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 22:41:40
User entered empty.	System	08 Sep 2020 22:41:40
	Chanei Henry (b) (4)	08 Sep 2020 22:41:40
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'None (NONE)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'I'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Cough x 1 day. Did not take any medications and symptom did not interfere with daily activities.'	(b) (4) Chanei Henry (b) (4)	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User entered '0'	System	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53
User entered '0'	System	08 Sep 2020 22:41:40

US3862020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:35:53

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:21:08
User closed query 'Per DM CLR: Please review AE and please update to specify whether AE of Chest Pain is Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 21:59:08
Query 'Per DM CLR: Please review AE and please update to specify whether AE of Chest Pain is Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'it is not related to either. investigator has linked AE to severe anemia/cancer related' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	25 Feb 2021 21:41:15
User opened query 'Per DM CLR: Please review AE and please update to specify whether AE of Chest Pain is Musculoskeletal or Respiratory -related condition. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:58:06
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:30:51
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'NO' (Site from DM).	Thea Marie Cordero (b) (4)	18 Nov 2020 15:20:29
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:23:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:16:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:16:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

1807 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Nov 2020 18:58:46
User closed query 'For coding purposes, please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term.' (Site from System).	System	09 Nov 2020 18:58:12
Query 'For coding purposes, please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term.' answered with 'Updated' (Site from System).	Shetel Anassi (b) (4)	09 Nov 2020 18:58:12
Coding entries removed.	Shetel Anassi (b) (4)	09 Nov 2020 18:58:04
User entered 'CHEST PAIN non cardiac' reason for change: Data Entry Error	Shetel Anassi (b) (4)	09 Nov 2020 18:58:04
User opened query 'For coding purposes, please enter the type of CHEST PAIN [Chest pain – cardiac or Non-cardiac chest pain or Musculoskeletal Chest Pain] in order that the term may be coded accurately. Please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	29 Oct 2020 23:32:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:08
Data point term sent to Coder	System	28 Oct 2020 18:56:26
User entered 'Chest pain'	Thea Marie Cordero (b) (4)	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	25 Feb 2021 21:41:23
User entered '8 Sep 2020'	(b) (4)	
	Thea Marie Cordero	28 Oct 2020 18:56:22
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User entered empty.	System	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '30 Sep 2020'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User entered empty.	System	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'No (N)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Not Related (NOT RELATED)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Not Related (NOT RELATED)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	28 Oct 2020 18:56:31
User entered '1' reason for change: Data Entry Error	System	28 Oct 2020 18:56:31
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Thea Marie Cordero	28 Oct 2020 18:56:31
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	System	28 Oct 2020 18:56:22
	Thea Marie Cordero	28 Oct 2020 18:56:22
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Thea Marie Cordero (b) (4)	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4)	28 Oct 2020 18:56:22
	Thea Marie Cordero	
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User entered '0'	System	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03
User entered '0'	System	28 Oct 2020 18:56:22

US3862020

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:03

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 01:21:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 01:21:43
	(b) (4)	
Data point term sent to Coder	System	25 Mar 2021 01:20:37
Coding entries removed.	Thea Marie Cordero	25 Mar 2021 01:20:02
	(b) (4)	
User entered 'IRON DEFICIENCY ANEMIA' reason for change: New Information	Thea Marie Cordero	25 Mar 2021 01:20:02
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 15:06:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 15:06:06
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 15:05:40
User entered 'Anemia'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '30 Oct 2020'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 15:04:51

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 15:04:51

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'I'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:04:51
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 15:04:51

US3862020

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 15:04:51

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:00:28
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:05:45
User entered 'USA-US121-2021-mRNA-1273-P301000001'	System	22 Jan 2021 15:05:26
User entered 'New'	(b) (4), (b) (6)	22 Jan 2021 15:05:26

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:13
User closed query 'Per medical records, diagnosis has been updated to medullary carcinoma. Please update.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:54:10
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'PV Query: Please provide the stage and type of gastric cancer, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:52:36
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Gastric neoplasms malignant, PT: Adenocarcinoma gastric, LLT: Adenocarcinoma gastric stage III - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:15:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:15:53
Query 'Per medical records, diagnosis has been updated to medullary carcinoma. Please update.' answered with 'Updated source document and EDC with appropriate dx and severity.' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:21:24
Query 'PV Query: Please provide the stage and type of gastric cancer, when available.' answered with 'Updated source document and EDC to new AE title.' (Site from Safety).	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:20:45
Data point term sent to Coder	System	18 Mar 2021 23:19:08
DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:18:11
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:18:11
User entered 'MEDULLARY GASTRIC ADENOCARCINOMA STAGE III' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:18:11
User opened query 'Per medical records, diagnosis has been updated to medullary carcinoma. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:49:24
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:05:47
User opened query 'PV Query: Please provide the stage and type of gastric cancer, when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:33:20

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Gastric neoplasms malignant, PT: Gastric cancer, LLT: Gastric cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:05:10
Data point term sent to Coder	System	21 Jan 2021 19:04:28
User entered 'gastric cancer'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:05:56
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:05:59
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:00
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:25
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:03:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 22:02:02
User entered '04 Jan 2021' reason for change: New Information	Thea Marie Cordero	25 Mar 2021 22:02:02
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' answered with 'SUBJECT UNABLE TO RECALL SPECIFIC EXACT DATE' (Site from Safety).	(b) (4)	25 Mar 2021 01:06:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 01:05:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 01:05:31
User entered 'UN Sep 2020' (non-conformant).	Thea Marie Cordero	25 Mar 2021 01:05:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 00:38:46
DataPoint Un-verified.	Thea Marie Cordero	23 Mar 2021 00:38:46
User entered 'UN Dec 2020' (non-conformant).	Thea Marie Cordero	23 Mar 2021 00:38:46
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:06:03
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:33:13
User entered '04 Jan 2021'	Sandra Francisco	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:04
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:06
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:35
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
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)	25 Mar 2021 14:51:26
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 'AE IS ONGOING' (Site from Safety).	Thea Marie Cordero	24 Mar 2021 23:48:31
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)	23 Mar 2021 17:00:41
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:06:11
User entered empty.	Sandra Francisco (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:12
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:38
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.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:09
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 14:19:24
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)	29 Jan 2021 12:33:03
User entered empty.	System	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:10
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:15
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:17
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:18
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:20
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:21
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:22
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:24
User entered empty.	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:25
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:26
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:28
User entered 'I'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:30
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:31
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:33
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:06:41
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User closed query 'Please update with medications listed in medical records.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:54:45
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:00:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:53:01
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 15:39:06
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:21:08
Query 'Please update with medications listed in medical records.' answered with 'SEE CONCOMITANT MEDICATION LIST' (Site from CRA).	Thea Marie Cordero (b) (4)	25 Mar 2021 01:21:39
DataPoint Un-verified.	Carrie Kibler (b) (4)	22 Mar 2021 22:49:02
User entered '1' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	22 Mar 2021 22:49:02
User opened query 'Please update with medications listed in medical records.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 22:57:30
DataPoint Verified.	(b) (4)	04 Feb 2021 23:06:43
User entered '0'	Sandra Francisco (b) (4) (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:49
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Hana El Sahly (b) (4)	16 Apr 2021 12:59:36 15 Apr 2021 21:40:28
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'CORRECTED' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:57:27
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:53:27
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:53:27
User entered '0' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:53:27
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 15:39:33
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:45:18
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:21:08
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Per monitor instruction, con procedures will be updated once further clarified guidelines are provided' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	18 Mar 2021 23:23:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

1907 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 05:15:17
	(b) (4), (b) (6)	04 Feb 2021 23:06:40
User entered 'I'	Sandra Francisco (b) (4)	21 Jan 2021 19:04:22
	(b) (4)	

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:53:27
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:03:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE IS ONGOING' (Site from Safety).	Thea Marie Cordero	24 Mar 2021 23:49:33
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:59:53
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:29:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'NOT RECOVERED, UNDERGOING CHEMOTHERAPY' (Site from Safety).	Thea Marie Cordero	23 Mar 2021 00:39:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 23:00:35
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:32:45

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Francisco (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:54
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered empty.	(b) (4) Sandra Francisco (b) (4)	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "EGD & BIOPSY." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 Apr 2021 12:46:08
	Thea Marie Cordero	29 Mar 2021 14:21:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:03:55
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)	26 Mar 2021 18:03:43
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 'NO SURGICAL INTERVENTION DONE . NO MEDICAL INTERVENTION DONE YET. ' (Site from Safety).	Thea Marie Cordero (b) (4)	25 Mar 2021 01:00:51

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' answered with ' 17 DEC 2020: HEMOGLOBIN 7.9 g/dL HEMATOCRIT 27.4% 19 OCT 2020: FERRITIN LEVEL 10.3 ng/mL 04 JAN 2021: EGD BIOPSY: INVASIVE POORLY DIFFERENTIATED ADENOCARCINOMA (MEDULLARY CARCINOMA) 04 JAN 2021: COLONOSCOPY: UNREMARKABLE 22 JAN 2021: CT CHEST/ABDOMEN/PELVIS: GASTRIC MASS INVOLVING THE GREATER CURVATURE OF GASTRIC BODY 6.4x 5.8 CM 19 FEB 2021: DIAGNOSTIC LAPAROSCOPY RESULT: GASTRIC MASS ATTACHED TO THE LEFT LOBE OF THE LIVER AND THE TRANSVERSE COLON 20 FEB 2021: MRI ABDOMEN: LARGE MASS INVOLVING THE GASTRIC BODY AND ANTRUM SIMILAR IN APPEARANCE COMPARED TO TO RECENT ABDOMINAL CT, POSSIBLY REACTIVE PERIPORTAL LYMPH NODES NOTED LABS: HER-2 NEGATIVE, CEA 62 ng/mL, MSI-H, PD-L1 DIFFUSE POSITIVE CLINICAL STAGE: cT4N1MO STAGE 111, NEGATIVE GENETIC TESTING FOR LYNCH SYNDROME ' (Site from Safety). User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety). User closed query 'PV Query: Please provide the stage and type of gastric cancer, when available.' (Site from Safety). User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety).	Thea Marie Cordero (b) (4)	25 Mar 2021 00:59:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 17:00:09
User closed query 'PV Query: Please provide the stage and type of gastric cancer, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:30:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:29:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

1913 of 2819

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that subject had "EGD & BIOPSY." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	23 Mar 2021 00:59:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' answered with 'DIAGNOSTIC PROCEDURES WERE ENTERED IN SOURCE DOCUMENT AND EDC' (Site from Safety).	Thea Marie Cordero (b) (4)	23 Mar 2021 00:58:03
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	23 Mar 2021 00:48:39

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User entered '20JAN2021 THE SUBJECT WAS UNDERGOING HIS ANNUAL CHECK UP IN DEC 2020 AND FOUND TO BE ANEMIC. AS PART OF ANEMIA W/U, EGD WAS DONE ON 04JAN2021. ULCERS IN HIS STOMACH WERE IDENTIFIED AND BIOPSIES WERE TAKEN WHICH REVEALED GASTRIC CANCER. HE IS SCHEDULED ON 3RD OF FEB TO GET CT ABD AND US GUIDED EGD. IN DEC, HE WAS FEELING UNUSUALLY TIRED, HAD VAGUE PAIN IN CHEST AREA AND THAT IS WHAT PROMPTED THE EVALUATION. HE LOST ~10LBS LATELY BUT HAS ALSO BEEN EATING BETTER AND EXERCISING. HIS (b) (6) ALSO HAD A DX OF GASTRIC CANCER @ AGE 77. BEING EVALUATED FOR GENETIC PREDISPOSITION A/P SAE OF GASTRIC CA: UNRELATED TO STUDY VACCINE. AGREED TO SIGN A RELEASE OF INFORMATION SO WE CAN OBTAIN THE MEDICAL RECORDS AND DISCUSS WITH HIS DOCTORS. 10 MAR 2021: MEDICAL RECORDS REVIEWED SUBJECT HAD DIAGNOSTIC LAPAROSCOPY ON 19 FEB 2021: GASTRIC MASS ATTACHED TO LEFT LOBE OF LIVER AND TRANSVERSE COLON' reason for change: Data Entry Error Query 'PV Query: Please provide the stage and type of gastric cancer, when available.' answered with 'stage and type provided in source and edc.' (Site from Safety).	Thea Marie Cordero (b) (4)	23 Mar 2021 00:48:39
User opened query 'PV Query: Please provide the stage and type of gastric cancer, when available.' answered with 'stage and type provided in source and edc.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	22 Mar 2021 22:45:40
User opened query 'PV Query: Please provide the stage and type of gastric cancer, when available.' (Site from Safety).	(b) (4), (b) (6)	21 Mar 2021 14:57:15
User opened query 'Per DM CLR: Narrative indicates that subject had "EGD & BIOPSY." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 05:15:28
	(b) (4), (b) (6)	04 Feb 2021 23:06:51

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test (esophagogastroduodenoscopy, biopsy, CT scan, genetic testing) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 12:32:52
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)	29 Jan 2021 12:32:39
User entered '20JAN2021	Sandra Francisco (b) (4)	21 Jan 2021 19:04:22
The subject was undergoing his annual check up in DEC 2020 and found to be anemic. As part of anemia w/u, EGD was done on 04JAN2021. Ulcers in his stomach were identified and biopsies were taken which revealed gastric cancer. He is scheduled on 3rd of Feb to get CT abd and US guided EGD.	(b) (4)	

In DEC, he was feeling unusually tired, had vague pain in chest area and that is what prompted the evaluation. He lost ~10lbs lately but has also been eating better and exercising. His (b) (6) also had a dx of gastric cancer @ age 77. Being evaluated for genetic predisposition

A/P SAE of gastric ca: unrelated to study vaccine.

Agreed to sign a release of information so we can obtain the medical records and discuss with his doctors.'

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 19:04:22

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
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)	30 Mar 2021 21:22:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 21:22:11
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 21:21:20
User entered 'UNCONTROLLED TYPE 2 DIABETES MELLITUS'	(b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

Severity

Audit	User	Time (GMT)
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates uncontrolled, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	18 Apr 2021 08:57:01
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates uncontrolled, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'UPGRADED SEVERITY TO MODERATE PER NP, THEA.' (Site from DM). Signature has been broken.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Per Query Resolution User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates uncontrolled, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM). User signature succeeded.	Carrie Kibler (b) (4)	06 Apr 2021 23:22:14
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Per Query Resolution User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates uncontrolled, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM). User signature succeeded.	Carrie Kibler (b) (4)	06 Apr 2021 23:21:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 21:20:44

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 17:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 17:26:27
Data point term sent to Coder	System	12 Apr 2021 16:33:59
User entered 'HYPOCALCEMIA'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User entered empty.	System	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 16:33:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 16:33:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 16:33:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User entered empty.	System	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User entered '0'	System	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09
User entered 'I'	System	12 Apr 2021 16:33:06

US3862020

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:09

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:00:04
User entered 'USA-US121-2021-mRNA-1273-P301000009'	System	03 May 2021 15:59:58
User entered 'New'	(b) (4), (b) (6)	03 May 2021 15:59:58

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 May 2021 16:23:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 May 2021 16:23:02
Data point term sent to Coder	System	30 Apr 2021 20:14:45
User entered 'SEVERE ANEMIA'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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	30 Apr 2021 20:14:45
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	30 Apr 2021 20:14:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Apr 2021 20:14:45
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		30 Apr 2021 20:14:45
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	30 Apr 2021 20:14:45
User entered '1' reason for change: New Information	(b) (4), (b) (6)	30 Apr 2021 20:14:45
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Apr 2021 20:14:18
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:14:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 20:14:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 20:14:45
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 20:14:18
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT ADMITED TO THE HOSPITAL WITH LOW HEMOGLOBIN LEVEL ON 28 APR 2021. HE WILL BE DISCHARGED ON 30 APR 2021.MEDICAL RECORDS WILL BE REQUESTED AFTER THE DISCHARGE DAY.'	(b) (4), (b) (6)	30 Apr 2021 20:22:44
reason for change: Data Entry Error		
User entered 'PARTICIPANT ADMITED TO THE HOSPITAL WITH LOW HEMOGLOBIN LEVEL ON 28 APR 2021. HE WILL BE DISCHARGED ON 30 APR 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 20:16:30
User entered 'PARTICIPANT ADMITED TO THE HOSPITAL WITH LOW HEMOGLOBIN LEVEL ON 28 APR 2021. HE WILL BE DISHARGED ON 30 APR 2021'	(b) (4), (b) (6)	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 20:14:18

US3862020

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 20:14:18

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:59:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:22:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:26:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:26:22
Data point term sent to Coder User entered 'lipitor'	System Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:25:05 17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'hyperlipidemia'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '40'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:40:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:24:57
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Signature has been broken.	Thea Marie Cordero	06 Apr 2021 21:28:57
User entered 'No (N)' reason for change: New Information	(b) (4)	06 Apr 2021 21:28:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Signature has been broken.	Thea Marie Cordero	06 Apr 2021 21:28:57
User entered '15 Feb 2021' reason for change: New Information	(b) (4)	06 Apr 2021 21:28:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User entered '1'	System	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User entered '1'	System	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:02
User entered '804 (804)'	System	17 Aug 2020 23:24:57

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
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)	17 Aug 2020 23:29:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:29:15
Data point term sent to Coder User entered 'lisinopril'	System Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:28:07 17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'hypertension'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '2.5'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:40:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:27:13
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Signature has been broken.	Thea Marie Cordero	06 Apr 2021 21:29:36
User entered 'No (N)' reason for change: New Information	(b) (4)	06 Apr 2021 21:29:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:27:23
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Signature has been broken.	Thea Marie Cordero	06 Apr 2021 21:29:36
User entered '15 Feb 2021' reason for change: New Information	Thea Marie Cordero	06 Apr 2021 21:29:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:27:23
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:27:13
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:27:23
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User entered '1'	System	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User entered '1'	System	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:07
User entered '804 (804)'	System	17 Aug 2020 23:27:13

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:29:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:29:15
Data point term sent to Coder	System	17 Aug 2020 23:28:07
User entered 'metformin'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'diabetes mellitus type 2'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '1000'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'twice daily (BID)' reason for change:	Carrie Kibler (b) (4)	17 Aug 2020 23:29:34
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:40:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:27:55
User entered 'un UNK 2018'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User entered '2'	System	17 Aug 2020 23:29:34
User entered '1'	System	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User entered '1'	System	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:10
User entered '804 (804)'	System	17 Aug 2020 23:27:55

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:30:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:30:16
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:29:11
User entered 'flomax'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'benign prostatic hyperplasia'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '0.4'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 00:40:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:28:23
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:28:23

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:28:23
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:28:23

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:28:23

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 23:28:23

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:30:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:30:16
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 23:29:09
User entered 'glipizide'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'diabetes mellitus type 2'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '5'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	17 Aug 2020 23:29:17
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	17 Aug 2020 23:29:00
User entered 'twice daily (BID)'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:29:17
	(b) (4)	
User entered 'o'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:40:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 23:29:00
User entered 'un Mar 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:17:22
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 21:17:22
User entered empty.	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:29:00
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 23:29:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 13:27:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 13:27:46
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 13:27:19
Coding entries removed.	Thea Marie Cordero	26 Mar 2021 13:26:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 15:07:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 15:07:07
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 15:06:41
User entered 'Iron supplement'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'IRON DEFICIENCY ANEMIA'	Thea Marie Cordero	26 Mar 2021 13:26:40
reason for change: New Information	(b) (4)	
User entered 'ANEMIA'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '325'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'twice daily (BID)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '30 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	0 Mar 2021 17:55:00
User entered '10 Nov 2020'	Thea Marie Cordero (b) (4)	18 Nov 2020 15:05:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered '0'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered empty.	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Nov 2020 15:05:45
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 15:05:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 15:05:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 15:05:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC CARBOXYMALTOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:25
Data point term sent to Coder	System	26 Mar 2021 13:29:20
Coding entries removed.	Thea Marie Cordero (b) (4)	26 Mar 2021 13:28:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC CARBOXYMALTOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:37:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:37:50
Data point term sent to Coder	System	11 Mar 2021 18:19:00
User entered 'Ferric carboxymaltose infusion'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'IRON DEFICIENCY ANEMIA'	Thea Marie Cordero	26 Mar 2021 13:28:37
reason for change: New Information	(b) (4)	
User entered 'anemia'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '750'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '13 Jan 2021'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '13 Jan 2021'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User entered empty.	System	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User entered empty.	System	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:17
User entered empty.	System	11 Mar 2021 18:18:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:23:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:23:22
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero	06 Apr 2021 21:22:39 06 Apr 2021 21:22:37
User signature succeeded.	(b) (4) Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:17
Data point term sent to Coder User entered 'fentanyl'	System Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:28:24 23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:45:20
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:22:42
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:22:37
User entered 'COLONOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:22:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:11:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'moderate sedation for colonoscopy'	Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '175'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'ug (ug)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User entered empty.	System	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User entered empty.	System	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:21
User entered empty.	System	23 Mar 2021 01:28:00

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:24:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:24:24
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero	06 Apr 2021 21:23:40 06 Apr 2021 21:23:26
User signature succeeded.	(b) (4) Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:30
Data point term sent to Coder User entered 'versed'	System Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:29:24 23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:51:57
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:23:40
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:23:26
User entered 'COLONOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:23:26
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:12:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'moderate sedation for colonoscopy'	Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '7'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User entered empty.	System	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User entered empty.	System	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User entered empty.	System	23 Mar 2021 01:28:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero (b) (4)	06 Apr 2021 21:25:43 06 Apr 2021 21:25:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:25:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:25:25
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero (b) (4)	06 Apr 2021 21:24:42 06 Apr 2021 21:24:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:16
Data point term sent to Coder User entered 'fentanyl'	System Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:30:25 23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:53:02
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'ENDOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:25:40
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:24:35
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:24:19
User entered 'COLONOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:24:19
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:12:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'moderate sedation for colonoscopy'	Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '100'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'ug (ug)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User entered empty.	System	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User entered empty.	System	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:36
User entered empty.	System	23 Mar 2021 01:29:32

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:36:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:36:50
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero	06 Apr 2021 21:27:44 06 Apr 2021 21:27:14
User signature succeeded.	(b) (4) Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:30
Data point term sent to Coder User entered 'VERSED'	System Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:30:25 23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:53:14
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'ENDOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:27:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:27:19
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:27:14
User entered 'ENDOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:27:14
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'moderate sedation for colonoscopy'	Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '4'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '04 Jan 2021'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Sandra Francisco (b) (4)	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User entered empty.	System	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User entered empty.	System	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:41
User entered empty.	System	23 Mar 2021 01:29:56

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE, PRODUCTSYNONYM: GOLYTELY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:12:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:12:43
Data point term sent to Coder	System	06 Apr 2021 21:28:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
Data point term sent to Coder	System	23 Mar 2021 01:38:26
User entered 'GOLYTELY BOWEL PREP'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:53:25
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	06 Apr 2021 21:28:21
Signature has been broken.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:28:16
User entered 'COLONOSCOPY' reason for change: New Information	Thea Marie Cordero (b) (4)	06 Apr 2021 21:28:16
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:13:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'BOWEL PREP FOR COLONOSCOPY'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '400'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mL (mL)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '03 Jan 2021'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '03 Jan 2021'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User entered empty.	System	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User entered empty.	System	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:45
User entered empty.	System	23 Mar 2021 01:37:59

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:10:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:10:47
Data point term sent to Coder	System	25 Mar 2021 01:19:37
User entered 'PACKED RED BLOOD CELL BLOOD TRANSFUSION'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'IRON DEFICIENCY ANEMIA'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '250'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mL (mL)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '19 Jan 2021'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '19 Jan 2021'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	Thea Marie Cordero (b) (4)	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User entered empty.	System	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User entered empty.	System	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:49
User entered empty.	System	25 Mar 2021 01:19:29

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:24:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:24:27
Data point term sent to Coder	System	30 Mar 2021 21:26:27
Data point term sent to Coder	System	30 Mar 2021 21:20:19
User entered 'GLIPIZIDE'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'UNCONTROLLED TYPE 2 DIABETES MELLITIS'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '10'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 21:25:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 21:25:31
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 21:25:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 21:19:30
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '13 Jan 2021'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User entered '2'	System	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User entered '1'	System	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:53
User entered '804 (804)'	System	30 Mar 2021 21:19:30

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 21:28:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 21:28:15
Data point term sent to Coder	System	30 Mar 2021 21:27:28
User entered 'TYLENOL EXTRA STRENGTH'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'PAIN POST PORTHA CATH INSERTION'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '1000'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Mar 2021 21:27:51
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 21:27:51
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Mar 2021 21:27:16
User entered 'as needed (PRN)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 21:27:51
User entered 'qhs'		30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '19 Feb 2021'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '23 Feb 2021'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User entered '3'	System	30 Mar 2021 21:27:51
User entered empty.	System	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User entered '1'	System	30 Mar 2021 21:27:51
User entered empty.	System	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:14:17
User entered '804 (804)'	System	30 Mar 2021 21:27:51
User entered empty.	System	30 Mar 2021 21:27:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User closed query 'Per CDM: As per previous DM CLR query, please review if the strength should be provided in the medication name. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:48:32
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE;PRILOCAINE, PRODUCTSYNONYM: EMLA [LIDOCAINE;PRILOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:04:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 04:04:47
Query 'Per CDM: As per previous DM CLR query, please review if the strength should be provided in the medication name. Thank you.' answered with 'Source verified. 2.5% entered into EDC medication name.' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	28 Apr 2021 20:33:56
Data point term sent to Coder	System	28 Apr 2021 20:33:36
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	28 Apr 2021 20:33:30
Signature has been broken.	Sandra Francisco (b) (4) (b) (4)	28 Apr 2021 20:33:30
User entered 'EMPLA CREAM 2.5%' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	28 Apr 2021 20:33:30
User opened query 'Per CDM: As per previous DM CLR query, please review if the strength should be provided in the medication name. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:28:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE;PRILOCAINE, PRODUCTSYNONYM: EMLA [LIDOCAINE;PRILOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:22:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[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. User signature succeeded.	Coder Import (b) (4) (b) (4) Hana El Sahly (b) (4)	08 Apr 2021 06:22:38 02 Apr 2021 14:05:00
Data point term sent to Coder	System	30 Mar 2021 21:30:31
User entered 'EMPLA CREAM'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'PORTH-A-CATH ACCESS'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name field and consider recording the number of applications as dose instead (e.g. dose=1; unit=application). Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:07:46
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name field and consider recording the number of applications as dose instead (e.g. dose=1; unit=application). Review and update as appropriate.' answered with 'data correction done ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 21:53:49
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 21:50:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:50:20
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name field and consider recording the number of applications as dose instead (e.g. dose=1; unit=application). Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:15:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '2.5'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Other (OTHER)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:03
User closed query 'Per CDM: As per above CLR query, please consider updating the unit field to "Application" and updating the strength into the medication name. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:28:08
Query 'Per CDM: As per above CLR query, please consider updating the unit field to "Application" and updating the strength into the medication name. Thank you.' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:26:05
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:25:57
User entered 'application' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:25:57
User opened query 'Per CDM: As per above CLR query, please consider updating the unit field to "Application" and updating the strength into the medication name. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:08:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'CONCENTRATION'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '22 Feb 2021'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '22 Feb 2021'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User entered empty.	System	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User entered empty.	System	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:18
User entered empty.	System	30 Mar 2021 21:29:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:28:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:28:22
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 21:31:31
User entered 'MULTVITAMINS'	(b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'ANEMIA'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 21:30:46

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:04:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:04:57
Data point term sent to Coder	System	09 Apr 2021 22:07:17
Coding entries removed.	(b) (4), (b) (6)	09 Apr 2021 22:07:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 21:33:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 21:33:20
Data point term sent to Coder	System	30 Mar 2021 21:32:33
User entered 'COMPAZINE'	(b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Hana El Sahly (b) (4)	26 Apr 2021 07:23:26 15 Apr 2021 21:40:28
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'SEE AE: MEDULLARY GASTRIC ADENOCARCINOMA STAGE III' (Site from DM). Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 22:08:08 09 Apr 2021 22:07:10
User entered 'CHEMOTHERAPY INDUCED-NAUSEA' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:07:10
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Hana El Sahly (b) (4)	07 Apr 2021 15:15:42 02 Apr 2021 14:05:00
User entered 'NAUSEA'	(b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '10'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:00
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 21:32:01

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 09:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:07:54
Data point term sent to Coder	System	09 Apr 2021 22:11:21
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'ONDANSETRON' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
Data point term sent to Coder	System	09 Apr 2021 22:09:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
Data point term sent to Coder	System	31 Mar 2021 19:45:01
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:44:41
User entered 'No (N)'		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'CHEMOTHERAPY INDUCED-NAUSEA' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered '8' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:44:41
User entered empty.		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'EVERY 8 HOURS AS NEEDED'	(b) (4)	09 Apr 2021 22:10:38
reason for change: Data Entry Error	(b) (4), (b) (6)	
DataPoint activated with code reason code Data		09 Apr 2021 22:08:54
required.		
DataPoint inactivated with code reason code Data not		31 Mar 2021 19:44:41
required.		
User entered empty.		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:44:41
User entered empty.		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System).		09 Apr 2021 22:10:38
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:44:41
User entered '0'		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:44:41
User entered empty.		31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:10:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:10:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:10:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 19:44:22
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User entered empty.	System	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User entered empty.	System	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 22:08:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:44:41
User entered empty.	System	31 Mar 2021 19:44:22

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 21:32:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 21:32:18
Data point term sent to Coder	System	06 Apr 2021 21:31:47
User entered 'GABAPENTIN'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'PERIPHERAL NEUROPATHY'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '100'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'three times daily (TID)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'UN Jun 2019'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'UN Jun 2019'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User entered '3'	System	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User entered '1'	System	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:26
User entered '804 (804)'	System	06 Apr 2021 21:31:31

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 08:33:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:33:35
Data point term sent to Coder	System	06 Apr 2021 21:33:53
User entered 'PANTOPRAZOLE'	Thea Marie Cordero (b) (4)	06 Apr 2021 21:32:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'PROPHYLAXIS FOR HEARTBURN'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '40'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'once daily (QD)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '17 Mar 2021'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '0'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	06 Apr 2021 21:32:48
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:32:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:32:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:32:48

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ANTIMETABOLITES, ATC: PYRIMIDINE ANALOGUES, PRODUCT: FLUOROURACIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 08:15:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 08:15:39
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 21:41:01
User entered 'FLUOROURACIL'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'MEDULLARY GASTRIC ADENOCARCINOMA STAGE III'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '4,800'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'other (OTHER)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'CONTINUOUS INFUSION VIA PORT CATH FOR 48 HOURS HRS'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '29 Mar 2021'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '0'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered '31 Mar 2021'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	06 Apr 2021 21:40:05
	(b) (4)	

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:40:05

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:40:05

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:40:05

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:07:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 08:07:43
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:36:02
User entered 'PACKED RBC TRANSFUSSION'	(b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'IRON DEFICIENCY ANEMIA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'UNIT'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:35:38

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Apr 2021 13:48:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:48:02
Data point term sent to Coder	System	12 Apr 2021 16:38:06
User entered 'CALCIUM GLUCONATE'	(b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'HYPOCALCEMIA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '1000'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:37:07

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:10:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 11:10:53
Data point term sent to Coder	System	12 Apr 2021 16:39:07
User entered 'DEXAMETHASONE'	(b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'MEDULARRY GASTRIC STAGE III ADENOCARCINOMA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '10'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:38:47

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: FERRIC CARBOXYMALTOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:47:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:47:01
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:41:11
User entered 'FERRIC CARBOXYMALTOSE'	(b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'IRON DEFICIENCY ANEMIA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '750'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 16:40:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 16:40:27
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:40:27
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 16:40:16
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:40:16

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
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, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 21:48:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 21:48:15
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 06:33:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 06:33:49
Data point term sent to Coder	System	12 Apr 2021 16:42:12
User entered '0.9% SODIUM CHLORIDE'	(b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'HYPOCALCEMIA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '50'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:42:23
User entered 'other (OTHER)' reason for change:	(b) (4), (b) (6)	12 Apr 2021 16:42:23
Data Entry Error		
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:42:10
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'ADMINISTRED WITH CALCIUM GLUCONATE'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:42:10

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH SODIUM BICARBONATE, PRODUCT: GLUCONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 06:36:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 06:36:41
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:44:21
User entered '0.9% SODOIM GLUCONATE'	(b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'IRON DEFICIENCY ANEMIA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '250'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'ADMINISTRED WITH FERRIC CARBOXYMALTOSE'	(b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:14

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: DETOXIFYING AGENTS FOR ANTINEOPLASTIC TREATMENT, PRODUCT: FOLINIC ACID, PRODUCTSYNONYM: LEUCOVORIN [FOLINIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:49:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:49:52
Data point term sent to Coder	System	12 Apr 2021 16:46:24
User entered 'LEUCOVORIN'	(b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'MEDULARRY GASTRIC III ADENOCARCINOMA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '800'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:45:35

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: PLATINUM COMPOUNDS, PRODUCT: OXALIPLATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:53:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:53:44
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:48:27
User entered 'OXALIPLATIN'	(b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'MEDULARRY GASTRIC III ADENOCARCINOMA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '170'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:47:50

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: PALONOSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:51:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 12:51:00
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:49:28
User entered 'PALONOSETRON'	(b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'MEDULARRY GASTRIC III ADENOCARCINOMA'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0.25'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:48:45

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
	(b) (4)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:50:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 13:50:50
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 16:58:37
User entered 'MAGNEZIUM SULFATE'	(b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'CHEMOTHERAPY INDUCED NEPHROTOXICITY PROPHYLAXIS'	(b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '1000'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:59:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:57:52

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:59:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 18:42:55

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:45:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'diagnostic laparoscopy'	(b) (4), (b) (6)	11 Mar 2021 18:45:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:45:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:45:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '19 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 18:46:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'port placement'	(b) (4), (b) (6)	11 Mar 2021 18:46:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Mar 2021 18:46:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:46:56

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '04 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 18:47:46

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'upper endoscopy'	(b) (4), (b) (6)	11 Mar 2021 18:47:46

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Mar 2021 18:47:46

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:47:46

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '04 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 18:48:17

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'gastric biopsy'	(b) (4), (b) (6)	11 Mar 2021 18:48:17

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Mar 2021 18:48:17

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:48:17

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '20 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 18:48:51

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'MRI abdomen'	(b) (4), (b) (6)	11 Mar 2021 18:48:51

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Mar 2021 18:48:51

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:48:51

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	11 Mar 2021 20:40:51
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 20:40:51
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	11 Mar 2021 20:40:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 20:40:36
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	11 Mar 2021 18:50:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 18:50:28
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	11 Mar 2021 18:49:54
User entered '22 Jan 2020'	(b) (4), (b) (6)	11 Mar 2021 18:49:54

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 20:40:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 18:50:28
User entered 'CT of Chest, Abdomen and pelvis'	(b) (4), (b) (6)	11 Mar 2021 18:49:54

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 20:40:36
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Mar 2021 18:50:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	11 Mar 2021 18:49:54

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Mar 2021 20:40:36
DataPoint inactivated with code reason code Data not required.		11 Mar 2021 18:50:28
User entered empty.		11 Mar 2021 18:49:54

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '04 Jan 2021'	Carrie Kibler (b) (4)	22 Mar 2021 23:10:43
	(b) (4)	

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'esophagogastroduodenoscopy with biopsy'	Carrie Kibler (b) (4)	22 Mar 2021 23:10:43

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	Carrie Kibler (b) (4)	22 Mar 2021 23:10:43

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	22 Mar 2021 23:10:43

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '04 Jan 2021'	Carrie Kibler (b) (4)	22 Mar 2021 23:15:53
	(b) (4)	

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'COLONOSCOPY WITH BIOPSY'	Carrie Kibler (b) (4)	22 Mar 2021 23:15:53

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	Carrie Kibler (b) (4)	22 Mar 2021 23:15:53

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:51:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Carrie Kibler (b) (4)	22 Mar 2021 23:15:53

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '04 Jan 2021'	Thea Marie Cordero (b) (4)	26 Mar 2021 13:30:05

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'MODERATE SEDATION'	Thea Marie Cordero (b) (4)	26 Mar 2021 13:30:05

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	26 Mar 2021 13:30:05

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:59:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	Thea Marie Cordero (b) (4)	26 Mar 2021 13:30:05

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:59:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	30 Mar 2021 21:16:25
User entered '22 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	30 Mar 2021 21:16:25
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	30 Mar 2021 21:15:34
User entered '22 Feb 2020'	(b) (4), (b) (6)	30 Mar 2021 21:15:34

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:59:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'PET/CT SCAN SKULL BASE TO MID THIGH'	(b) (4), (b) (6)	30 Mar 2021 21:15:34

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:59:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Mar 2021 21:15:34

US3862020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:59:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:15:34

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
User entered '22/Jan/2021 10:05'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'I'		22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '19/Mar/2021 11:53'	(b) (4) System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'I'		19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '19/Mar/2021 12:20'	(b) (4) System	19 Mar 2021 16:20:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'I'		19 Mar 2021 16:20:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '23/Mar/2021 09:32'	(b) (4) System	23 Mar 2021 16:32:37

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'I'		23 Mar 2021 16:32:37

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '25/Mar/2021 09:52'	(b) (4) System	25 Mar 2021 14:52:32

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:11:35
User entered 'I'		25 Mar 2021 14:52:32

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
User entered '26/Mar/2021 14:04'	(b) (4) System	26 Mar 2021 18:04:29

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:04:33
User entered 'I'		26 Mar 2021 18:04:29

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'USA-US121-2021-MRNA-1273-P301000001'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4)	22 Jan 2021 16:18:49
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'No (N)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'Yes (Y)'	System	22 Jan 2021 15:05:26

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Thea Marie'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Cordero'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'Houston'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered 'TX'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:51:49
User entered '77030'	System	19 Mar 2021 15:53:02

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:18:49
Reviewed for Safety.		22 Jan 2021 15:05:57
User entered 'US'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 13:12:08
User entered '6'	System	26 Mar 2021 18:04:29
User entered '5'	System	25 Mar 2021 14:52:32
User entered '4'	System	23 Mar 2021 16:32:37
User entered '3'	System	19 Mar 2021 16:20:26
User entered '2'	System	19 Mar 2021 15:53:02
User entered '1'	System	22 Jan 2021 15:05:44

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
User entered '07/Apr/2021 06:12'	(b) (4) System	07 Apr 2021 13:12:08

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:12:08

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'USA-US121-2021-MRNA-1273-P301000009'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Yes (Y)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Yes (Y)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Thea Marie'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Cordero'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Houston'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'TX'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered '77030'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
User entered 'US'	(b) (4) System	03 May 2021 16:00:51

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 16:00:51

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'USA-US121-2021-MRNA-1273-P301000009'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Yes (Y)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Yes (Y)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'No (N)'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Thea Marie'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Cordero'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered 'Houston'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4)	03 May 2021 16:00:30
User entered 'TX'	(b) (4), (b) (6) System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 16:00:30
User entered '77030'	System	03 May 2021 15:59:58

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
User entered 'US'	(b) (4) System	03 May 2021 16:00:51

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 16:00:51

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
User entered '03/May/2021 12:00'	(b) (4) System	03 May 2021 16:00:51

US3862020

Folder: SAE USA-US121-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:43

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.	Hana El Sahly (b) (4)	03 May 2021 19:17:45
User entered 'I'	(b) (4), (b) (6)	03 May 2021 16:00:51