

US3862021 (Prod: Baylor College of Medicine)

Generated By: (b) (6)

Generated On: 11 Jun 2021 15:03:34

All time stamps listed in this document are displayed in GMT

US3862021

Form: Participant Creation

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

Generated On: 11 Jun 2021 15:03:34

Participant ID

US3862021

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

US3862021

Folder: Screening

Form: Visit Date

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

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	17 AUG 2020

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

Folder OID	SCRN

US3862021

Folder: Screening

Form: Demographics

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

Generated On: 11 Jun 2021 15:03:34

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	56
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3862021

Folder: Screening

Form: Enrollment

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

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 11 Jun 2021 15:03:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3862021

Folder: Screening

Form: Medical History Summary

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

Generated On: 11 Jun 2021 15:03:34

Were any significant conditions reported?

Yes ☒

No ☐

US3862021

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862021

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	21 MAY 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862021

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN MAY 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862021

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862021

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	HYPERTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3862021

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	THYROID I131 ABLATION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3862021

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	BACTRIM ALLERGY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862021

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3862021

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	STATIN INTOLERANT (RHABDOMYOLYSIS)
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3862021

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 29 Mar 2021 15:53:47

Generated On: 11 Jun 2021 15:03:34

Condition	SULFA ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3862021

Folder: Screening

Form: Vital Signs

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

Generated On: 11 Jun 2021 15:03:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:27
Height (xxx.x)	73 in
Weight (xxx.x)	256.6 lb
BMI (xxx.x)	33.92508 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862021

Folder: Screening

Form: Physical Examination

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

Generated On: 11 Jun 2021 15:03:34

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.

US3862021

Folder: Screening

Form: Risk of Exposure

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

Generated On: 11 Jun 2021 15:03:34

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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

Generated On: 11 Jun 2021 15:03:34

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	

US3862021

Folder: Visit 1 Day 1

Form: Visit Date

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

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3862021

Folder: Visit 1 Day 1

Form: Randomization

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

Generated On: 11 Jun 2021 15:03:34

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

What was the participant's randomization number? 143528

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:27
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	094 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 16:16
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3862021

Folder: Visit 1 Day 1

Form: Physical Examination

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

Generated On: 11 Jun 2021 15:03:34

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.

US3862021

Folder: Visit 1 Day 1

Form: Exposure

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

Generated On: 11 Jun 2021 15:03:34

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) 15:46 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 15:46

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

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

Generated On: 11 Jun 2021 15:03:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy) 17 AUG 2020

Collection time (00:00-23:59) 14:13 (24 HR)

Collection date and time (derived) 17 AUG 2020 14:13

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

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

Generated On: 11 Jun 2021 15:03:34

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	13:46	17 AUG 2020 13:46
Nasopharyngeal Swab 2	No		

US3862021

Folder: Visit 1 Day 1

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

97.6 °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 16:08

PC Open Date & Time

17 AUG 2020 16:06

PC Close Date & Time

17 AUG 2020 18:36

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	17 AUG 2020 19:57
PC Open Date & Time	17 AUG 2020 19:31
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

18 AUG 2020 16:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

96.3 °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

19 AUG 2020 13:47

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:53

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

21 AUG 2020 16:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

22 AUG 2020 22:28

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

24 AUG 2020 00:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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 16:07

PC Open Date & Time

17 AUG 2020 16:06

PC Close Date & Time

17 AUG 2020 18:36

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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 19:52

PC Open Date & Time

17 AUG 2020 19:31

PC Close Date & Time

18 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

5

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:16

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 3
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 - SWELLING/HARDNESS AT INJECTION SITE (in mm)	5
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below	None ☒
	Does not interfere with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 AUG 2020 13:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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 21:53

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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 16:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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 22:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

24 AUG 2020 00:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 16:08
PC Open Date & Time	17 AUG 2020 16:06
PC Close Date & Time	17 AUG 2020 18:36

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 19:53
PC Open Date & Time	17 AUG 2020 19:31
PC Close Date & Time	18 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	18 AUG 2020 16:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

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EAB) (1725)

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	19 AUG 2020 13:48
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	20 AUG 2020 21:54
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

60 of 2819

EAB) (1725)

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	21 AUG 2020 16:11
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

62 of 2819

EAB) (1725)

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	22 AUG 2020 22:15
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2819

EAB) (1725)

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	24 AUG 2020 00:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3862021

Folder: Safety Call Day 8 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Safety Call Day 8 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 15 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 15 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 22 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

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

CONTACT NOT MADE DUE TO
HOLIDAY

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 22 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 15:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	17:53 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 17:53
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3862021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 17:21 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 17:21

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

US3862021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	14 SEP 2020

Collection time (00:00-23:59)	16:25 (24 HR)

Collection date and time (derived)	14 SEP 2020 16:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)			14 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	14:10	14 SEP 2020 14:10

US3862021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:47

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

97.6 °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

14 SEP 2020 17:54

PC Open Date & Time

14 SEP 2020 17:41

PC Close Date & Time

14 SEP 2020 20:11

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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 100.1 °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	15 SEP 2020 09:54
PC Open Date & Time	14 SEP 2020 21:06
PC Close Date & Time	15 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	16 SEP 2020 01:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

99.6 °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 SEP 2020 09:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 16:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

18 SEP 2020 18:43

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

95.8 °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 13:28

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

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.

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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

95.9 °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 12:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

14 SEP 2020 17:55

PC Open Date & Time

14 SEP 2020 17:41

PC Close Date & Time

14 SEP 2020 20:11

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☒

No ☐

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 09:57

PC Open Date & Time

14 SEP 2020 21:06

PC Close Date & Time

15 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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 ☐

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

1

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

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 01:51

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

17 SEP 2020 09:36

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

17 SEP 2020 15:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

18 SEP 2020 18:44

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

19 SEP 2020 13:29

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

20 SEP 2020 12:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 17:55
PC Open Date & Time	14 SEP 2020 17:41
PC Close Date & Time	14 SEP 2020 20:11

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 09:57
PC Open Date & Time	14 SEP 2020 21:06
PC Close Date & Time	15 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

EAB) (1725)

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US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	16 SEP 2020 01:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

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 ☒

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	17 SEP 2020 09:38
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	17 SEP 2020 15:50
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

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)

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US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	18 SEP 2020 18:56
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

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EAB) (1725)

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	19 SEP 2020 13:29
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

Yes ☐	
PC Time stamp	20 SEP 2020 12:55
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3862021

Folder: Safety Call Day 36 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Safety Call Day 36 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 43 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 43 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 50 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 50 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:18
Temperature (xxx.x)	098.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	073 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3862021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	11:54 (24 HR)
Collection date and time (derived)	19 OCT 2020 11:54

US3862021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:32:49

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	17 OCT 2020 00:31:21
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

26 OCT 2020 13:46:18

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 06:58:18

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 00:03:40

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 04:31:23
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

26 NOV 2020 05:42:02

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 00:21:55
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 00:36:47
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

16 DEC 2020 04:12:28

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:02:55

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

30 DEC 2020 00:08:51

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 20:25:58
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 01:30:58

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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	22 JAN 2021 01:59:48
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 12:33:32

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 02:04:38

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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	10 FEB 2021 00:24:37
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 00:20:48

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 07:46:48

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 06:29:31
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 00:58:10

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 00:03:50
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

Date and time of submission

24 MAR 2021 00:14:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 00:42:57
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 00:53:33
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 00:02:27

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

21 APR 2021 00:02:24

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 00:17:39

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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12 SEP 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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19 SEP 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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26 SEP 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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03 OCT 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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10 OCT 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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13 OCT 2021 00:01

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17 OCT 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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24 OCT 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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27 OCT 2021 00:01

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31 OCT 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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07 NOV 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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14 NOV 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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17 NOV 2021 00:01

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21 NOV 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

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28 NOV 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

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26 DEC 2021 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

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02 JAN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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16 JAN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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23 JAN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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06 FEB 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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13 FEB 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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20 FEB 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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27 FEB 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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16 MAR 2022 00:01

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20 MAR 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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27 MAR 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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08 MAY 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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11 MAY 2022 00:01

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15 MAY 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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22 MAY 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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25 MAY 2022 00:01

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29 MAY 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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05 JUN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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08 JUN 2022 00:01

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12 JUN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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19 JUN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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29 JUN 2022 00:01

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03 JUL 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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10 JUL 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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17 JUL 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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27 JUL 2022 00:01

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31 JUL 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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07 AUG 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

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14 AUG 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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17 AUG 2022 00:01

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21 AUG 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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28 AUG 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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°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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

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31 AUG 2022 00:01

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04 SEP 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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°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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3862021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Jun 2021 15:03:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 06:29:22

US3862021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:25:15

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:25:15

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

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 ONLY ONE ATTEMPT MADE. PD
CREATED.

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	12 MAR 2021

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

Folder OID	VISIT4

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 11:13
Temperature (xxx.x)	097.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	070 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	094 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	057 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3862021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 MAR 2021

Collection time (00:00-23:59) 11:31 (24 HR)

Collection date and time (derived) 12 MAR 2021 11:31

US3862021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 239 (1)

Form: Safety Call

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

Generated On: 11 Jun 2021 15:03:34

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 UNABLE TO REACH PARTICIPANT.

If Contact Not Made, please provide Comments

US3862021

Folder: Safety Call Day 239 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862021

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:03:34

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3862021

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 15:03:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3862021

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	11 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3862021

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 18:32:19

Generated On: 11 Jun 2021 15:03:34

Date of updated informed consent (dd MMM yyyy) 11 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3862021

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:05:38

Generated On: 11 Jun 2021 15:03:34

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	11 JAN 2021

Collection time (00:00-23:59)	13:25 (24 HR)

Collection date and time (derived)	11 JAN 2021 13:25

US3862021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:05:38

Generated On: 11 Jun 2021 15:03:34

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	11 JAN 2021

Collection time (00:00 - 23:59)	13:21

Collection Date and Time (derived)	11 JAN 2021 13:21

US3862021

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:11:26

Generated On: 11 Jun 2021 15:03:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Jun 2021 15:03:34

AEID	USA-US121-2020-MRNA-1273-P30 1000002
Adverse event	INFEROLATERAL STEMI
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)	4 OCT 2020
Start time (00:00-23:59)	00:45 (24 HR)
AE start date and time (derived)	4 OCT 2020 00:45
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	7 OCT 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	4 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	7 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐

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EAB) (1725)

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US3862021

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Jun 2021 15:03:34

Number of Days in ICU	2
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Jun 2021 15:03:34

AT MIDNIGHT ON OCTOBER 3,
PARTICIPANT WAS
EXPERIENCING CHEST PAIN
THAT WAS RADIATING TO HIS
ARM, DIAPHORESIS, AND
BLURRY VISION. HE WENT
STRAIGHT TO THE
EMERGENCY ROOM. PENDING
MEDICAL RELEASE
INFORMATION FROM
HOSPITAL. 06OCT2020 SAE
SUMMARY: AS ABOVE. PAST
MEDICAL HISTORY OBTAINED
DURING SCREENING AND
ENROLLMENT INCLUDED
HISTORY OF A ROUTINE
STRESS TEST IN JUN 2019 WITH
A POSITIVE FINDING. A
FOLLOW UP CARDIAC
CATHETERIZATION WAS DONE.
THERE WAS NO SURGICAL
INTERVENTION. NO
ADDITIONAL PERTINENT
MEDICAL HISTORY WAS
PROVIDED. 10OCT2020
SAE UPDATE #1: PER PHONE
INTERVIEW WITH SUBJECT.
SUBJECT REPORTS TO HAVE
BEEN DOING WELL WITH
ROUTINE CARDIOLOGY VISIT 1
WEEK PRIOR TO EVENT.
WALKED 4.5MILES THAT DAY
WITHOUT PAIN OR SHORTNESS
OF BREATH. REPORTS TO HAVE
UNDERGONE CARDIAC

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Jun 2021 15:03:34

CATHETERIZATION WITH
FINDING OF RUPTURED
PLAQUE AND PLACEMENT OF 3
STENTS. MEDICATIONS WERE
ADJUSTED. NO
SIGNS/SYMPTOMS OF
COVID-19, AND A SCREENING
TEST ON ADMISSION WAS
NEGATIVE. AFTER DISCHARGE,
SUBJECT FOLLOWED UP WITH
CARDIOLOGIST ON 09 OCT 2020,
AND PLANS TO RETURN IN 2
WEEKS FOR STRESS TEST.
RELEASE OF INFORMATION
REQUESTED FOR PERMISSION
TO OBTAIN MEDICAL RECORDS
FROM HOSPITAL AND
CARDIOLOGISTS.

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)	1

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Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 11 Jun 2021 15:03:34

AEID	
Adverse event	LOW CORTISOL LEVEL
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)	04 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)	
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	

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Folder: Adverse Events

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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) _____	

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Folder: Adverse Events

Form: Adverse Events (3)

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

Generated On: 11 Jun 2021 15:03:34

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)

14 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

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

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:05:38

Generated On: 11 Jun 2021 15:03:34

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication NOVOLOG 70/30

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	10	OCT 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication NORVASC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	05 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHROIDISM

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 13:58:24

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	9 FEB 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 13:58:24

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Name of Medication TOPROL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 13:58:24

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	05	OCT 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication CYTOMEL

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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

MONDAY-FRIDAY ONE TIME
EACH OF THOSE DAYS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication CYTOMEL

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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

SATURDAY AND SUNDAY ONE
TIME EACH OF THOSE DAYS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ZETIA

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	9 FEB 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50,000

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 TEN DAYS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	06 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication OLMESARTAN
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication IMDUR

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	03 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE SWELLING

Dose per administration 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER AND INJECTION SITE PAIN

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	16 SEP 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication BRILINTA

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR EVENT
PREVENTION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication TOPROL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication NORVASC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication PRALUENT

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 150

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

ONCE EVERY TWO WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

Dose per administration 80

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

If dose unit is Other, specify UNITS PER KG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication INTEGRILIN

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication BRILINTA

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ADENOSINE

Prophylaxis Yes ☐
No ☒

Indication DURING PCI FOR
INFEROLATERAL STEMI

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication INTRAVENOUS CONTRAST

Prophylaxis Yes ☐
No ☒

Indication DURING PCI

Dose per administration 190

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	04 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication INTRAVENOUS NORMAL
SALINE SOLUTION (BOLUS)

Prophylaxis Yes ☐
No ☒

Indication DURING PCI FOR
INFEROLATERAL STEMI

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication INFEROLATERAL STEMI

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
CONSTIPATION DURING
HOSPITALIZATION FOR
INFEROLATERAL STEMI

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR DEEP VEIN
THROMBOSIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication HYDRATION DURING
HOSPITALIZATION FOR
INFEROLATERAL STEMI

Dose per administration 75

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

If dose unit is Other, specify ML/HOUR

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 IV HYDRATION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication SODIUM CHLORIDE - SALINE
FLUSH0.9%

Prophylaxis Yes ☐
No ☒

Indication FOR IV FLUSH

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

EVERY 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication NIACIN EXTENDED RELEASE

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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)

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US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication SENNOSIDE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
CONSTIPATION DURING
HOSPITALIZATION FOR
INFERO LATERAL STEM

Dose per administration 8.6

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

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

Q 10 DAYS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 04 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication CARDIZEM

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 240

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication HYDROCORTISONE

Prophylaxis Yes ☐
No ☒

Indication LOW CORTISOL LEVEL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 0.75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication TDAP

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF TETANUS AND
DIFTERIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

Name of Medication MMR II

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF MUMPS,
MEASLES, RUBELLA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 23 Apr 2021 13:58:24

Generated On: 11 Jun 2021 15:03:34

	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 AUG 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:05:38

Generated On: 11 Jun 2021 15:03:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 14:05:38

Generated On: 11 Jun 2021 15:03:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 OCT 2020	PERCUTANEOUS CORONARY INTERVENTION (PCI)	Adverse Event	
04 OCT 2020	INTRAVASCULAR ULTRASOUND (IV US)	Adverse Event	
04 OCT 2020	LEFT HEART CATHERIZATION	Adverse Event	
04 OCT 2020	SELECTIVE CORONARY ANGIOGRAM	Adverse Event	
04 OCT 2020	ULTRASOUND GUIDED ACCESS THROUGH RIGHT FEMORAL ARTERY	Adverse Event	
05 OCT 2020	TRANSTHORACIC ECHOCARDIOGRAM WITH DOPPLER	Adverse Event	
04 OCT 2020	CHEST X RAY	Adverse Event	
04 OCT 2020	EKG	Adverse Event	

US3862021

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:03:34

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

US3862021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 15:03:34

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 ☐

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

SAEID	USA-US121-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

SAEID	USA-US121-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/OCT/2020 14:38
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

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

SAEID	USA-US121-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/OCT/2020 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

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

SAEID	USA-US121-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 15:46
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

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 14:05:39

Generated On: 11 Jun 2021 15:03:34

SAEID	USA-US121-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/NOV/2020 21:47
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

US3862021 (Prod: Baylor College of Medicine)

US3862021

Form: Participant Creation

Generated On: 11 Jun 2021 15:03:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'US3862021'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:09

US3862021

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:50:23

US3862021

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:10

US3862021

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4)	17 Aug 2020 20:50:23

US3862021

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'SCRN'	System	17 Aug 2020 20:50:23

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:11

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '55'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'YEARS'	System	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '56'	System	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Male (M)'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '1'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:03:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:09

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Aug 2020'	System	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2020'	System	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Amendment 2 (2)'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:26

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:49:10

US3862021

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:03:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '1'	System	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 15:03:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 20:40:50
User closed query 'Thyroid ablation is noted in source since it is significant to Hyperthyroidism. Please update EDC.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 20:40:48
Query 'Thyroid ablation is noted in source since it is significant to Hyperthyroidism. Please update EDC.' answered with 'completed' (Site from CRA).	Sandra Francisco (b) (4)	10 Nov 2020 23:16:22
User opened query 'Thyroid ablation is noted in source since it is significant to Hyperthyroidism. Please update EDC.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:51:50
Query 'Thyroid ablation is noted in source since it is significant to Hyperthyroidism. Please update EDC.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:50:50
User opened query 'Thyroid ablation is noted in source since it is significant to Hyperthyroidism. Please update EDC.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:25:35
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:36:08

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:53:47
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Mar 2021 22:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 22:35:51
Data point term sent to Coder	System	22 Mar 2021 22:34:53
Signature has been broken.	(b) (4), (b) (6)	22 Mar 2021 22:34:52
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:40:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:40:11
Data point term sent to Coder	System	17 Aug 2020 22:39:58
User entered 'CORONARY ARTERY DISEASE'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:53:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:34:18
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'UN UNK 2019'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:53:47
Signature has been broken.	(b) (4)	22 Mar 2021 18:08:15
User signature succeeded.	Sandra Francisco (b) (4)	13 Feb 2021 00:32:47
User entered '0'	(b) (4)	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:39:56
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:53:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:33:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:53:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:33:59
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2019'	System	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2019'	System	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:39:56

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
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 22:42:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:42:14
Data point term sent to Coder	System	17 Aug 2020 22:41:05
User entered 'DIABETES MELLITUS TYPE 2'	Carrie Kibler (b) (4)	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '21 May 2010'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:40:52
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:40:52
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'May 2010'	System	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2010'	System	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:40:52

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
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 22:43:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:43:15
Data point term sent to Coder	System	17 Aug 2020 22:42:07
User entered 'HYPERTENSION'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'UN May 2011'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:18
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:18
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'May 2011'	System	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2011'	System	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:41:18

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:43:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:43:15
Data point term sent to Coder	System	17 Aug 2020 22:42:05
User entered 'HYPOTHYROIDISM'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'UN UNK 2008'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:41:46
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2008'	System	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2008'	System	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:41:46

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Per DM CLR: Please note, stop date of MH = UN UNK 2008. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:09:09
Query 'Per DM CLR: Please note, stop date of MH = UN UNK 2008. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:58:21
User opened query 'Per DM CLR: Please note, stop date of MH = UN UNK 2008. However, no procedure or treatment recorded for this condition. Review and update medical history as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:33:01
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:44:16
Data point term sent to Coder	System	17 Aug 2020 22:43:08
User entered 'HYPERTHYROIDISM'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'UN UNK 2008'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	24 Dec 2020 19:27:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 18:58:09
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2008' reason for change: Data Entry Error	Carrie Kibler (b) (4)	24 Dec 2020 19:27:02
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 18:58:09
User entered 'UN UNK 2008'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:11
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2008'	System	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2008'	System	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2008'	System	24 Dec 2020 19:27:02
User entered empty.	System	27 Oct 2020 18:58:09
User entered 'Jan 2008'	System	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2008'	System	24 Dec 2020 19:27:02
User entered empty.	System	27 Oct 2020 18:58:09
User entered '2008'	System	17 Aug 2020 22:42:11

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
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 22:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:44:16
Data point term sent to Coder	System	17 Aug 2020 22:43:09
User entered 'HYPERLIPIDEMIA'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'UN UNK 2016'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:33
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:33
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:42:33
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2016'	System	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2016'	System	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	17 Aug 2020 22:42:33

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
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)	03 Nov 2020 18:57:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:57:24
Data point term sent to Coder	System	03 Nov 2020 18:57:08
Coding entries removed.	Shetel Anassi (b) (4)	03 Nov 2020 18:56:45
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	(b) (4)	
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	Shetel Anassi (b) (4)	03 Nov 2020 18:56:45
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: BPH - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 21:47:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 21:47:51
Data point term sent to Coder	System	14 Sep 2020 21:46:56
User entered 'bph'	Carrie Kibler (b) (4)	14 Sep 2020 21:46:43
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2017'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	14 Sep 2020 21:46:43
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2017'	System	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2017'	System	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	14 Sep 2020 21:46:43

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:57:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 18:57:25
Data point term sent to Coder	System	03 Nov 2020 18:57:08
User entered 'VITAMIN D DEFICIENCY'	Shetel Anassi (b) (4)	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2015'	Shetel Anassi (b) (4)	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Shetel Anassi (b) (4) (b) (4)	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Shetel Anassi (b) (4) (b) (4)	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Shetel Anassi (b) (4)	03 Nov 2020 18:56:15
	(b) (4)	

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2015'	System	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2015'	System	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	03 Nov 2020 18:56:15

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid radiotherapies, PT: Radioactive iodine therapy, LLT: Thyroid remnant ablation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 07:05:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 07:05:45
Data point term sent to Coder	System	10 Nov 2020 23:15:18
Coding entries removed.	Sandra Francisco (b) (4)	10 Nov 2020 23:14:25
User entered 'THYROID I131 ABLATION' reason for change: Data Entry Error	(b) (4)	
User entered 'thyroid ablation'	Sandra Francisco (b) (4)	10 Nov 2020 23:14:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroid therapy, LLT: Thyroid therapy - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:13:45
Data point term sent to Coder	System	10 Nov 2020 23:13:12
User entered 'thyroid ablation'	Sandra Francisco (b) (4)	10 Nov 2020 23:12:17
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2008'	Sandra Francisco (b) (4)	10 Nov 2020 23:12:17

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Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Sandra Francisco (b) (4)	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2008'	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2008'	System	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2008'	System	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2008'	System	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2008'	System	10 Nov 2020 23:12:17

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 17:34:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 17:34:23
Data point term sent to Coder	System	30 Jan 2021 17:33:53
User entered 'bactrim allergy'	Sandra Francisco (b) (4)	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2018'	Sandra Francisco (b) (4)	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	30 Jan 2021 17:33:44

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Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2018'	System	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2018'	System	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:33:44

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 17:35:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 17:35:23
Data point term sent to Coder	System	30 Jan 2021 17:34:54
User entered 'seasonal allergies'	Sandra Francisco (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'un UNK 2014'	Sandra Francisco (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'Jan 2014'	System	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '2014'	System	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:03

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Myopathies, PT: Rhabdomyolysis, LLT: Rhabdomyolysis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:47:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:47:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
Data point term sent to Coder	System	30 Jan 2021 17:34:54
User entered 'statin intolerant (rhabdomyolysis)'	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '1'	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Jan 2021 17:34:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Jan 2021 17:34:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Jan 2021 17:34:53
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Jan 2021 17:34:45
User entered empty.	Sandra Francisco (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:34:45

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 17:36:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 17:36:23
Data point term sent to Coder	System	30 Jan 2021 17:35:54
User entered 'sulfa allergy'	Sandra Francisco (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '1'	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Sandra Francisco (b) (4)	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered empty.	System	30 Jan 2021 17:35:06

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '13:27'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 13:27'	System	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '73' in	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '256.6' lb	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
DataPoint set to visible.	(b) (4) System	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Amendment Manager: User entered '33.92508'	System	17 Sep 2020 00:00:49
User entered '33.9'	System	17 Aug 2020 22:37:09
DataPoint set to visible.	System	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'kg/m2'	System	17 Aug 2020 22:37:09
DataPoint set to visible.	System	17 Aug 2020 20:51:47

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '97.8' F	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Other (Other)'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'TEMPORAL'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '94'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'bpm'	System	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '16'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'breaths/min'	System	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '101'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09
	(b) (4)	

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'mmHg'	System	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '73'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered 'mmHg'	System	17 Aug 2020 22:37:09

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:50:56

US3862021

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56

US3862021

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:14

US3862021

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:05:56
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:02:15
User entered '17 Aug 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:14

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0' reason for change: Data Entry Error	Carrie Kibler (b) (4)	24 Dec 2020 19:13:44
User entered '1'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4)	24 Dec 2020 19:13:44
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:03:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:37:47
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:49:42

US3862021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:49:42

US3862021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[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 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:49:42

US3862021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'VISIT1'	System	17 Aug 2020 20:49:42

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:17:18

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:08:35
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:08:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 20:17:18
User entered '143528' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:17:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 20:17:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:44:23

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:44:23

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:44:23
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:44:23

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:44:23
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Chanei Henry (b) (4)	21 Sep 2020 19:11:10
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:23:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:44:05

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:02:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 15:13:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 15:13:16
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:17:57
User entered '73' in	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 15:13:16
User entered '256.6' lb	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:02:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 15:13:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 15:13:16
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:17:57
User entered '73' in	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 15:13:16
User entered '256.6' lb	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:54:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 20:54:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:11
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:53:46
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:11
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '13:27' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '17 Aug 2020 13:27'	System	17 Aug 2020 20:54:11
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '97.8' F reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:35
User entered 'Other (Other)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Temporal' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 20:54:35
User entered '094' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'bpm'	System	17 Aug 2020 20:54:35
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 20:54:35
User entered '16' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'breaths/min'	System	17 Aug 2020 20:54:35
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 20:54:35
User entered '101' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'mmHg'	System	17 Aug 2020 20:54:35
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 20:54:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 20:54:35
User entered '073' reason for change: Data Entry Error	Sandra Francisco (b) (4)	17 Aug 2020 20:54:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 20:54:11
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'mmHg'	System	17 Aug 2020 20:54:35
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:02:04
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 15:13:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 15:13:16
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:17:57
User entered '73' in	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:03:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 15:13:16
User entered '256.6' lb	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Per CDM: Per site response on "Vital Signs form at Screening", site reports the Post-Dose vital signs were assessed on 17Aug2020. Please verify data and update the "Post-Dose Vital Signs Dosing form at Visit 1 Day 1", to include date of assessment, time of assessment, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 08:40:53
Query 'Per CDM: Per site response on "Vital Signs form at Screening", site reports the Post-Dose vital signs were assessed on 17Aug2020. Please verify data and update the "Post-Dose Vital Signs Dosing form at Visit 1 Day 1", to include date of assessment, time of assessment, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure. Thank you.' answered with 'Done' (Site from DM).	Chanei Henry (b) (4) (b) (4)	24 Aug 2020 16:13:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Chanei Henry (b) (4) (b) (4)	24 Aug 2020 16:10:37
Query 'Per CDM: Per site response on Vital Signs form at Screening, site reports the Post-Dose vital signs were assessed on 17Aug2020. Please verify data and update the Post Dose Vital Signs Dosing form at Visit 1 Day 1, to include date of assessment, time of assessment, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 01:24:16
User opened query 'Per CDM: Per site response on "Vital Signs form at Screening", site reports the Post-Dose vital signs were assessed on 17Aug2020. Please verify data and update the "Post-Dose Vital Signs Dosing form at Visit 1 Day 1", to include date of assessment, time of assessment, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 01:23:57

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per site response on Vital Signs form at Screening, site reports the Post-Dose vital signs were assessed on 17Aug2020. Please verify data and update the Post Dose Vital Signs Dosing form at Visit 1 Day 1, to include date of assessment, time of assessment, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure. Thank you.' (Site from DM). Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 01:22:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 01:13:44
User entered empty.	System	17 Aug 2020 20:53:46
	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46
	(b) (4)	

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '16:16' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '17 Aug 2020 16:16'	System	24 Aug 2020 16:10:37
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '97.6' F reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Other (Other)' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Temporal' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '80' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'bpm'	System	24 Aug 2020 16:10:37
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '16' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'breaths/min'	System	24 Aug 2020 16:10:37
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '112' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'mmHg'	System	24 Aug 2020 16:10:37
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '74' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Aug 2020 16:10:37
User entered empty.	Sandra Francisco (b) (4)	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'mmHg'	System	24 Aug 2020 16:10:37
User entered empty.	System	17 Aug 2020 20:53:46

US3862021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:56:32

US3862021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:56:32

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '15:46'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '17 Aug 2020 15:46'	System	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4)	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'ONCE'	System	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:52:43

US3862021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	17 Aug 2020 20:56:52

US3862021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:56:52

US3862021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '14:13'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:56:52

US3862021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '17 Aug 2020 14:13'	System	17 Aug 2020 20:56:52

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17 Aug 2020'	Sandra Francisco (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Francisco (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '13:46'	Sandra Francisco (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '17 Aug 2020 13:46'	System	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Francisco (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Sandra Francisco (b) (4) (b) (4)	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered empty.	System	17 Aug 2020 20:57:08

US3862021

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 15:54:17

US3862021

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	24 Aug 2020 15:54:17

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:07:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a760951f-c4c3-425d-b8d5-a9860da6caed' User entered 'Yes (Y)'	System	17 Aug 2020 21:08:17
	System	17 Aug 2020 21:08:17

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a760951f-c4c3-425d-b8d5-a9860da6caed' User entered '97.6'	System	17 Aug 2020 21:08:17
	System	17 Aug 2020 21:08:17

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:12', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a760951f-c4c3-425d-b8d5-a9860da6caed' User entered 'No (N)'	System	17 Aug 2020 21:08:17
	System	17 Aug 2020 21:08:17

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a760951f-c4c3-425d-b8d5-a9860da6caed' User entered '17 Aug 2020 16:08'	System	17 Aug 2020 21:08:17
	System	17 Aug 2020 21:08:17

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 16:06'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 18:36'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:56:50', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c9f58ba3-cda8-407e-8a5a-369c5a021274' User entered 'Yes (Y)'	System	18 Aug 2020 00:57:09
	System	18 Aug 2020 00:57:09

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:56:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c9f58ba3-cda8-407e-8a5a-369c5a021274' User entered '97.9'	System	18 Aug 2020 00:57:09
	System	18 Aug 2020 00:57:09

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:57:03', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c9f58ba3-cda8-407e-8a5a-369c5a021274' User entered 'No (N)'	System	18 Aug 2020 00:57:09
	System	18 Aug 2020 00:57:09

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:57:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c9f58ba3-cda8-407e-8a5a-369c5a021274' User entered '17 Aug 2020 19:57'	System	18 Aug 2020 00:57:09
	System	18 Aug 2020 00:57:09

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 19:31'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 2'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:20:24', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '24fd9960-ca32-4450-8707-a2d1aafc88c3' User entered 'Yes (Y)'	System	18 Aug 2020 21:20:43
	System	18 Aug 2020 21:20:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:20:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '24fd9960-ca32-4450-8707-a2d1aafc88c3' User entered '97.7'	System	18 Aug 2020 21:20:43
	System	18 Aug 2020 21:20:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:20:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '24fd9960-ca32-4450-8707-a2d1aafc88c3'	System	18 Aug 2020 21:20:43
User entered 'No (N)'	System	18 Aug 2020 21:20:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:20:39', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '24fd9960-ca32-4450-8707-a2d1aafc88c3' User entered '18 Aug 2020 16:20'	System	18 Aug 2020 21:20:43
	System	18 Aug 2020 21:20:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 3'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4e7dcce9-9e3d-4937-86eb-ca2a2875a7a9' User entered 'Yes (Y)'	System	19 Aug 2020 18:47:16
	System	19 Aug 2020 18:47:16

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:07', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4e7dcce9-9e3d-4937-86eb-ca2a2875a7a9' User entered '96.3'	System	19 Aug 2020 18:47:16
	System	19 Aug 2020 18:47:16

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:10', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4e7dcce9-9e3d-4937-86eb-ca2a2875a7a9'	System	19 Aug 2020 18:47:16
User entered 'No (N)'	System	19 Aug 2020 18:47:16

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4e7dcce9-9e3d-4937-86eb-ca2a2875a7a9' User entered '19 Aug 2020 13:47'	System	19 Aug 2020 18:47:16
	System	19 Aug 2020 18:47:16

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 4'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '78875717-366f-4ec0-af84-db5e458f4ce2'	System	21 Aug 2020 02:53:36
User entered 'Yes (Y)'	System	21 Aug 2020 02:53:36

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '78875717-366f-4ec0-af84-db5e458f4ce2' User entered '98.3'	System	21 Aug 2020 02:53:36
	System	21 Aug 2020 02:53:36

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '78875717-366f-4ec0-af84-db5e458f4ce2'	System	21 Aug 2020 02:53:36
User entered 'No (N)'	System	21 Aug 2020 02:53:36

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:34', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '78875717-366f-4ec0-af84-db5e458f4ce2'	System	21 Aug 2020 02:53:36
User entered '20 Aug 2020 21:53'	System	21 Aug 2020 02:53:36

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 5'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:09:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '95ae8731-b4fe-42a6-aa46-bee21e598bbc' User entered 'Yes (Y)'	System	21 Aug 2020 21:10:11
	System	21 Aug 2020 21:10:11

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:09:59', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '95ae8731-b4fe-42a6-aa46-bee21e598bbc' User entered '96.8'	System	21 Aug 2020 21:10:11
	System	21 Aug 2020 21:10:11

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '95ae8731-b4fe-42a6-aa46-bee21e598bbc'	System	21 Aug 2020 21:10:11
User entered 'No (N)'	System	21 Aug 2020 21:10:11

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:09', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '95ae8731-b4fe-42a6-aa46-bee21e598bbc'	System	21 Aug 2020 21:10:11
User entered '21 Aug 2020 16:10'	System	21 Aug 2020 21:10:11

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 6'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:28:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3f28d7e3-d247-4fe0-9109-0aab3c3e64c6' User entered 'Yes (Y)'	System	23 Aug 2020 03:28:28
	System	23 Aug 2020 03:28:28

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:28:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3f28d7e3-d247-4fe0-9109-0aab3c3e64c6' User entered '97.2'	System	23 Aug 2020 03:28:28
	System	23 Aug 2020 03:28:28

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:28:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3f28d7e3-d247-4fe0-9109-0aab3c3e64c6'	System	23 Aug 2020 03:28:28
User entered 'No (N)'	System	23 Aug 2020 03:28:28

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:28:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3f28d7e3-d247-4fe0-9109-0aab3c3e64c6' User entered '22 Aug 2020 22:28'	System	23 Aug 2020 03:28:28
	System	23 Aug 2020 03:28:28

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 7'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '271bdb1d-015c-4f0d-8943-e17f7b2728a6' User entered 'Yes (Y)'	System	24 Aug 2020 05:05:46
	System	24 Aug 2020 05:05:46

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '271bdb1d-015c-4f0d-8943-e17f7b2728a6' User entered '97.3'	System	24 Aug 2020 05:05:46
	System	24 Aug 2020 05:05:46

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:37', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '271bdb1d-015c-4f0d-8943-e17f7b2728a6' User entered 'No (N)'	System	24 Aug 2020 05:05:46
	System	24 Aug 2020 05:05:46

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '271bdb1d-015c-4f0d-8943-e17f7b2728a6' User entered '24 Aug 2020 00:05'	System	24 Aug 2020 05:05:46
	System	24 Aug 2020 05:05:46

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:06:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '75582ad5-aaf2-4c70-973d-30cd03f1cf0c'	System	17 Aug 2020 21:07:14
User entered 'None (1)'	System	17 Aug 2020 21:07:14

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:06:34', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '75582ad5-aaf2-4c70-973d-30cd03f1cf0c' User entered 'No (N)'	System	17 Aug 2020 21:07:14
	System	17 Aug 2020 21:07:14

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:06:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '75582ad5-aaf2-4c70-973d-30cd03f1cf0c' User entered 'No (N)'	System	17 Aug 2020 21:07:14
	System	17 Aug 2020 21:07:14

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:06:59', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '75582ad5-aaf2-4c70-973d-30cd03f1cf0c'	System	17 Aug 2020 21:07:14
User entered 'None (1)'	System	17 Aug 2020 21:07:14

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:07:10', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '75582ad5-aaf2-4c70-973d-30cd03f1cf0c' User entered '17 Aug 2020 16:07'	System	17 Aug 2020 21:07:14
	System	17 Aug 2020 21:07:14

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 16:06'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 18:36'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b20dc758-a43b-4eae-bae0-578277f1da23'	System	18 Aug 2020 00:52:34
User entered 'None (1)'	System	18 Aug 2020 00:52:34

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:21', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b20dc758-a43b-4eae-bae0-578277f1da23'	System	18 Aug 2020 00:52:34
User entered 'No (N)'	System	18 Aug 2020 00:52:34

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:24', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b20dc758-a43b-4eae-bae0-578277f1da23' User entered 'No (N)'	System	18 Aug 2020 00:52:34
	System	18 Aug 2020 00:52:34

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:28', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b20dc758-a43b-4eae-bae0-578277f1da23'	System	18 Aug 2020 00:52:34
User entered 'None (1)'	System	18 Aug 2020 00:52:34

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:31', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b20dc758-a43b-4eae-bae0-578277f1da23' User entered '17 Aug 2020 19:52'	System	18 Aug 2020 00:52:34
	System	18 Aug 2020 00:52:34

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 19:31'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 2'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:15:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261'	System	18 Aug 2020 21:16:48
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:15:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261' User entered 'No (N)'	System	18 Aug 2020 21:16:48
	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:15:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261' User entered 'Yes (Y)'	System	18 Aug 2020 21:16:48
	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:35', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261' User entered '5'	System	18 Aug 2020 21:16:48
	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261'	System	18 Aug 2020 21:16:48
User entered 'None (1)'	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e896ffb9-e278-4153-b808-809489d8a261' User entered '18 Aug 2020 16:16'	System	18 Aug 2020 21:16:48
	System	18 Aug 2020 21:16:48

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 3'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered 'None (1)'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:24', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered 'No (N)'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:34', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered 'Yes (Y)'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:39', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered '5'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered 'None (1)'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd3277d8c-cbd6-4661-8653-01d26513483b' User entered '19 Aug 2020 13:47'	System	19 Aug 2020 18:48:08
	System	19 Aug 2020 18:48:08

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 4'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:52:39', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '28c09f41-4c4c-4147-946d-13535e6b0512'	System	21 Aug 2020 02:53:22
User entered 'None (1)'	System	21 Aug 2020 02:53:22

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:52:42', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '28c09f41-4c4c-4147-946d-13535e6b0512'	System	21 Aug 2020 02:53:22
User entered 'No (N)'	System	21 Aug 2020 02:53:22

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:52:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '28c09f41-4c4c-4147-946d-13535e6b0512' User entered 'No (N)'	System	21 Aug 2020 02:53:22
	System	21 Aug 2020 02:53:22

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:52:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '28c09f41-4c4c-4147-946d-13535e6b0512'	System	21 Aug 2020 02:53:22
User entered 'None (1)'	System	21 Aug 2020 02:53:22

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:05', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '28c09f41-4c4c-4147-946d-13535e6b0512'	System	21 Aug 2020 02:53:22
User entered '20 Aug 2020 21:53'	System	21 Aug 2020 02:53:22

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 5'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2e3973cf-d49a-4a89-a0e3-dfa7d2e32c42'	System	21 Aug 2020 21:10:49
User entered 'None (1)'	System	21 Aug 2020 21:10:49

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2e3973cf-d49a-4a89-a0e3-dfa7d2e32c42'	System	21 Aug 2020 21:10:49
User entered 'No (N)'	System	21 Aug 2020 21:10:49

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2e3973cf-d49a-4a89-a0e3-dfa7d2e32c42'	System	21 Aug 2020 21:10:49
User entered 'No (N)'	System	21 Aug 2020 21:10:49

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2e3973cf-d49a-4a89-a0e3-dfa7d2e32c42'	System	21 Aug 2020 21:10:49
User entered 'None (1)'	System	21 Aug 2020 21:10:49

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2e3973cf-d49a-4a89-a0e3-dfa7d2e32c42'	System	21 Aug 2020 21:10:49
User entered '21 Aug 2020 16:10'	System	21 Aug 2020 21:10:49

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 6'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:27', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '823cc700-8e91-473d-8528-ae96b1060ba9' User entered 'None (1)'	System	23 Aug 2020 03:16:01
	System	23 Aug 2020 03:16:01

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '823cc700-8e91-473d-8528-ae96b1060ba9' User entered 'No (N)'	System	23 Aug 2020 03:16:01
	System	23 Aug 2020 03:16:01

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:50', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '823cc700-8e91-473d-8528-ae96b1060ba9' User entered 'No (N)'	System	23 Aug 2020 03:16:01
	System	23 Aug 2020 03:16:01

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:54', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '823cc700-8e91-473d-8528-ae96b1060ba9' User entered 'None (1)'	System	23 Aug 2020 03:16:01
	System	23 Aug 2020 03:16:01

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '823cc700-8e91-473d-8528-ae96b1060ba9' User entered '22 Aug 2020 22:15'	System	23 Aug 2020 03:16:01
	System	23 Aug 2020 03:16:01

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 7'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b7d59e4-5d56-4169-838f-032754242cf9' User entered 'None (1)'	System	24 Aug 2020 05:06:04
	System	24 Aug 2020 05:06:04

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b7d59e4-5d56-4169-838f-032754242cf9' User entered 'No (N)'	System	24 Aug 2020 05:06:04
	System	24 Aug 2020 05:06:04

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b7d59e4-5d56-4169-838f-032754242cf9' User entered 'No (N)'	System	24 Aug 2020 05:06:04
	System	24 Aug 2020 05:06:04

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:05:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b7d59e4-5d56-4169-838f-032754242cf9' User entered 'None (1)'	System	24 Aug 2020 05:06:04
	System	24 Aug 2020 05:06:04

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b7d59e4-5d56-4169-838f-032754242cf9' User entered '24 Aug 2020 00:06'	System	24 Aug 2020 05:06:04
	System	24 Aug 2020 05:06:04

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356'	System	17 Aug 2020 21:08:51
User entered 'None (0)'	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356'	System	17 Aug 2020 21:08:51
User entered 'None (0)'	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:30', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356' User entered 'None (0)'	System	17 Aug 2020 21:08:51
	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356' User entered 'None (0)'	System	17 Aug 2020 21:08:51
	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356'	System	17 Aug 2020 21:08:51
User entered 'None (0)'	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356'	System	17 Aug 2020 21:08:51
User entered 'None (0)'	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:46', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356' User entered 'No (N)'	System	17 Aug 2020 21:08:51
	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T16:08:49', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2a0179e4-b765-4b96-b0c9-418d87673356'	System	17 Aug 2020 21:08:51
User entered '17 Aug 2020 16:08'	System	17 Aug 2020 21:08:51

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 16:06'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 18:36'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:49', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:52:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'None (0)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:53:07', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered 'No (N)'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-17T19:53:11', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '4a7d5a1b-949d-400a-8853-e8a576f5dba1' User entered '17 Aug 2020 19:53'	System	18 Aug 2020 00:53:14
	System	18 Aug 2020 00:53:14

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Aug 2020 19:31'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 2'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:49', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:16:59', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:17:02', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:17:05', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'None (0)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:17:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered 'No (N)'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-18T16:17:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1f748c04-c09f-4354-a95d-d9c7b37ea8fd' User entered '18 Aug 2020 16:17'	System	18 Aug 2020 21:17:22
	System	18 Aug 2020 21:17:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 3'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:47:59', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:48:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:48:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:48:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'None (0)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:48:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered 'No (N)'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-19T13:48:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'da4839d8-c5d6-453c-b7e5-5d9ee160e237' User entered '19 Aug 2020 13:48'	System	19 Aug 2020 18:48:22
	System	19 Aug 2020 18:48:22

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 4'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:49', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:51', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:54', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'None (0)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:53:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered 'No (N)'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-20T21:54:10', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '77ad80f1-1c5a-4c30-b3b5-04810c24d46f' User entered '20 Aug 2020 21:54'	System	21 Aug 2020 02:54:11
	System	21 Aug 2020 02:54:11

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 5'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:54', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3' User entered 'None (0)'	System	21 Aug 2020 21:11:20
	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3'	System	21 Aug 2020 21:11:20
User entered 'None (0)'	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:10:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3'	System	21 Aug 2020 21:11:20
User entered 'None (0)'	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:11:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3' User entered 'None (0)'	System	21 Aug 2020 21:11:20
	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:11:02', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3'	System	21 Aug 2020 21:11:20
User entered 'None (0)'	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:11:07', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3' User entered 'None (0)'	System	21 Aug 2020 21:11:20
	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:11:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3' User entered 'No (N)'	System	21 Aug 2020 21:11:20
	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-21T16:11:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '813c5bd8-bff9-43ff-a8cc-98c89c83f3b3' User entered '21 Aug 2020 16:11'	System	21 Aug 2020 21:11:20
	System	21 Aug 2020 21:11:20

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 6'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:14:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:14:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:14:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:02', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'None (0)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617' User entered 'No (N)'	System	23 Aug 2020 03:15:23
	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-22T22:15:21', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '288fb4ac-0725-4a07-bbee-cd22f7ac0617'	System	23 Aug 2020 03:15:23
User entered '22 Aug 2020 22:15'	System	23 Aug 2020 03:15:23

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 7'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:10', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:13', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'None (0)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered 'No (N)'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-08-24T00:06:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9e931316-9398-43dc-a53d-90104fb2cf5e' User entered '24 Aug 2020 00:06'	System	24 Aug 2020 05:06:21
	System	24 Aug 2020 05:06:21

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:52:43

US3862021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 16:03:27

US3862021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 16:03:27
	(b) (4)	

US3862021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	24 Aug 2020 16:03:27

US3862021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 16:03:27
	(b) (4)	

US3862021

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 16:03:34

US3862021

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	24 Aug 2020 16:03:34

US3862021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	01 Sep 2020 21:56:47

US3862021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '01 Sep 2020' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	10 Nov 2020 14:15:45
User entered '1 Sep 2020'	Chanei Henry (b) (4)	01 Sep 2020 21:56:47

US3862021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	01 Sep 2020 21:56:47

US3862021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Chanei Henry (b) (4)	01 Sep 2020 21:56:47
	(b) (4)	

US3862021

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	01 Sep 2020 21:56:54

US3862021

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	01 Sep 2020 21:56:54

US3862021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:01:51
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:01:26
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:01:26

US3862021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:01:26

US3862021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:01:51
User entered 'Contact Not Made (CONTACT NOT MADE)'	Carrie Kibler (b) (4)	14 Sep 2020 22:01:26

US3862021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact not made due to holiday'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:01:26

US3862021

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:00:59

US3862021

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	14 Sep 2020 22:00:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:15

US3862021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:15
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[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 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:15
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'VISIT2'	System	14 Sep 2020 22:02:15

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '15:45' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '14:56'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '14 Sep 2020 15:45'	System	14 Sep 2020 22:38:44
User entered empty.	System	14 Sep 2020 22:05:11
User entered '14 Sep 2020 14:56'	System	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '97.9' F reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '98.1' F	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '84' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '72'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'bpm'	System	14 Sep 2020 22:38:44
User entered empty.	System	14 Sep 2020 22:05:11
User entered 'bpm'	System	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '16' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '16'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'breaths/min'	System	14 Sep 2020 22:38:44
User entered empty.	System	14 Sep 2020 22:05:11
User entered 'breaths/min'	System	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '112' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '120'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	14 Sep 2020 22:38:44
User entered empty.	System	14 Sep 2020 22:05:11
User entered 'mmHg'	System	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:38:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Sep 2020 22:38:44
User entered '80' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:38:44
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:05:11
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:05:11
User entered '72'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	14 Sep 2020 22:38:44
User entered empty.	System	14 Sep 2020 22:05:11
User entered 'mmHg'	System	14 Sep 2020 22:03:52

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '14 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '17:53'	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '14 Sep 2020 17:53'	System	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '97.6' F	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Other (Other)'	Sandra Francisco (b) (4) (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Temporal'	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '83'	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'bpm'	System	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '16'	Sandra Francisco (b) (4) (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'breaths/min'	System	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '115'	Sandra Francisco (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '82'	Sandra Francisco (b) (4) (b) (4)	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	14 Sep 2020 23:03:59

US3862021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:04:01

US3862021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:04:01
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:39:02
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 22:39:02
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:11:33
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:02:58
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:58
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '17:21' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:39:02
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:11:33
User entered '16:58'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '14 Sep 2020 17:21'	System	14 Sep 2020 22:39:02
User entered empty.	System	14 Sep 2020 22:11:33
User entered '14 Sep 2020 16:58'	System	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:58
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'ONCE'	System	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 22:02:58

US3862021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:13

US3862021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:13
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:39:11
User entered '16:25' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:39:11
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:12:16
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:12:16
User entered '15:59'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:13

US3862021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '14 Sep 2020 16:25'	System	14 Sep 2020 22:39:11
User entered empty.	System	14 Sep 2020 22:12:16
User entered '14 Sep 2020 15:59'	System	14 Sep 2020 22:03:13

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:25
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'No (N)'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:25
	(b) (4)	

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered empty.	System	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:39:20
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Sep 2020 22:39:20
User entered '14:10' reason for change: Data Entry Error	Sandra Francisco (b) (4)	14 Sep 2020 22:39:20
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 22:12:43
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Sep 2020 22:12:43
User entered '15:26'	Carrie Kibler (b) (4)	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 22:39:20
User entered empty.	System	14 Sep 2020 22:12:43
User entered '14 Sep 2020 15:26'	System	14 Sep 2020 22:03:25

US3862021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:02:28

US3862021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	14 Sep 2020 22:02:28

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9af0a518-3113-47c2-9c7b-8145d8614879' User entered 'Yes (Y)'	System	14 Sep 2020 22:54:35
	System	14 Sep 2020 22:54:35

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9af0a518-3113-47c2-9c7b-8145d8614879' User entered '97.6'	System	14 Sep 2020 22:54:35
	System	14 Sep 2020 22:54:35

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9af0a518-3113-47c2-9c7b-8145d8614879' User entered 'No (N)'	System	14 Sep 2020 22:54:35
	System	14 Sep 2020 22:54:35

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9af0a518-3113-47c2-9c7b-8145d8614879' User entered '14 Sep 2020 17:54'	System	14 Sep 2020 22:54:35
	System	14 Sep 2020 22:54:35

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 17:18'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 20:11'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:54:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0b24d10f-ee66-409e-b510-7d81f5862268' User entered 'Yes (Y)'	System	15 Sep 2020 14:54:48
	System	15 Sep 2020 14:54:48

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:54:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0b24d10f-ee66-409e-b510-7d81f5862268' User entered '100.1'	System	15 Sep 2020 14:54:48
	System	15 Sep 2020 14:54:48

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:54:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0b24d10f-ee66-409e-b510-7d81f5862268' User entered 'No (N)'	System	15 Sep 2020 14:54:48
	System	15 Sep 2020 14:54:48

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:54:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0b24d10f-ee66-409e-b510-7d81f5862268' User entered '15 Sep 2020 09:54'	System	15 Sep 2020 14:54:48
	System	15 Sep 2020 14:54:48

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 21:06'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 20:43'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 2'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:48:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered 'Yes (Y)'	System	16 Sep 2020 06:50:37
	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered '98.2'	System	16 Sep 2020 06:50:37
	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered 'Yes (Y)'	System	16 Sep 2020 06:50:37
	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Documented' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 11:00:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered '1'	Chanei Henry (b) (4) (b) (4)	23 Sep 2020 18:39:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 06:50:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered '1'	System	16 Sep 2020 06:50:37
User entered '1'	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered '0'	System	16 Sep 2020 06:50:37
	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:35', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0147fa41-a99d-4d66-956a-216a11bada96' User entered '16 Sep 2020 01:50'	System	16 Sep 2020 06:50:37
	System	16 Sep 2020 06:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 3'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b2aaecf-8338-4ce6-95c1-37be4cb2d2fb' User entered 'Yes (Y)'	System	17 Sep 2020 14:37:30
	System	17 Sep 2020 14:37:30

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b2aaecf-8338-4ce6-95c1-37be4cb2d2fb' User entered '99.6'	System	17 Sep 2020 14:37:30
	System	17 Sep 2020 14:37:30

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:26', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b2aaecf-8338-4ce6-95c1-37be4cb2d2fb'	System	17 Sep 2020 14:37:30
User entered 'No (N)'	System	17 Sep 2020 14:37:30

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7b2aaecf-8338-4ce6-95c1-37be4cb2d2fb' User entered '17 Sep 2020 09:37'	System	17 Sep 2020 14:37:30
	System	17 Sep 2020 14:37:30

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 4'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T16:01:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '43542c92-6ba1-472c-a7fe-2f03c9f0c782'	System	17 Sep 2020 21:01:38
User entered 'Yes (Y)'	System	17 Sep 2020 21:01:38

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T16:01:27', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '43542c92-6ba1-472c-a7fe-2f03c9f0c782' User entered '96.5'	System	17 Sep 2020 21:01:38
	System	17 Sep 2020 21:01:38

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T16:01:30', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '43542c92-6ba1-472c-a7fe-2f03c9f0c782'	System	17 Sep 2020 21:01:38
User entered 'No (N)'	System	17 Sep 2020 21:01:38

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T16:01:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '43542c92-6ba1-472c-a7fe-2f03c9f0c782'	System	17 Sep 2020 21:01:38
User entered '17 Sep 2020 16:01'	System	17 Sep 2020 21:01:38

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 5'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:43:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8490d46b-ecb0-44e7-bf1e-f47adb253873' User entered 'Yes (Y)'	System	18 Sep 2020 23:43:58
	System	18 Sep 2020 23:43:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:43:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8490d46b-ecb0-44e7-bf1e-f47adb253873' User entered '96.3'	System	18 Sep 2020 23:43:58
	System	18 Sep 2020 23:43:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:43:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8490d46b-ecb0-44e7-bf1e-f47adb253873' User entered 'No (N)'	System	18 Sep 2020 23:43:58
	System	18 Sep 2020 23:43:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:43:51', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8490d46b-ecb0-44e7-bf1e-f47adb253873' User entered '18 Sep 2020 18:43'	System	18 Sep 2020 23:43:58
	System	18 Sep 2020 23:43:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 6'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:35', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '38ccd1d9-fdae-4b93-84e8-3ed86ef3e932' User entered 'Yes (Y)'	System	19 Sep 2020 18:28:51
	System	19 Sep 2020 18:28:51

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '38ccd1d9-fdae-4b93-84e8-3ed86ef3e932' User entered '95.8'	System	19 Sep 2020 18:28:51
	System	19 Sep 2020 18:28:51

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '38ccd1d9-fdae-4b93-84e8-3ed86ef3e932'	System	19 Sep 2020 18:28:51
User entered 'No (N)'	System	19 Sep 2020 18:28:51

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:50', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '38ccd1d9-fdae-4b93-84e8-3ed86ef3e932' User entered '19 Sep 2020 13:28'	System	19 Sep 2020 18:28:51
	System	19 Sep 2020 18:28:51

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 7'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '74fcb777-18d9-491f-b530-2f2ada0051ab' User entered 'Yes (Y)'	System	20 Sep 2020 17:54:16
	System	20 Sep 2020 17:54:16

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '74fcb777-18d9-491f-b530-2f2ada0051ab' User entered '95.9'	System	20 Sep 2020 17:54:16
	System	20 Sep 2020 17:54:16

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:09', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '74fcb777-18d9-491f-b530-2f2ada0051ab' User entered 'No (N)'	System	20 Sep 2020 17:54:16
	System	20 Sep 2020 17:54:16

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:12', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '74fcb777-18d9-491f-b530-2f2ada0051ab' User entered '20 Sep 2020 12:54'	System	20 Sep 2020 17:54:16
	System	20 Sep 2020 17:54:16

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:37', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '22ca1e9d-90dc-442d-86c8-9469c4e5909b' User entered 'None (1)'	System	14 Sep 2020 22:55:05
	System	14 Sep 2020 22:55:05

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '22ca1e9d-90dc-442d-86c8-9469c4e5909b' User entered 'No (N)'	System	14 Sep 2020 22:55:05
	System	14 Sep 2020 22:55:05

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:54:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '22ca1e9d-90dc-442d-86c8-9469c4e5909b' User entered 'No (N)'	System	14 Sep 2020 22:55:05
	System	14 Sep 2020 22:55:05

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '22ca1e9d-90dc-442d-86c8-9469c4e5909b' User entered 'None (1)'	System	14 Sep 2020 22:55:05
	System	14 Sep 2020 22:55:05

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:03', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '22ca1e9d-90dc-442d-86c8-9469c4e5909b' User entered '14 Sep 2020 17:55'	System	14 Sep 2020 22:55:05
	System	14 Sep 2020 22:55:05

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 17:18'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 20:11'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:54:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750'	System	15 Sep 2020 14:57:08
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:55:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered 'Yes (Y)'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:55:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered '5'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:55:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered 'Yes (Y)'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:56:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered '4'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:02', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered 'None (1)'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c7a276c0-ae6f-47a5-88e8-3b220bdc5750' User entered '15 Sep 2020 09:57'	System	15 Sep 2020 14:57:08
	System	15 Sep 2020 14:57:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 21:06'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 20:43'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 2'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:43', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4'	System	16 Sep 2020 06:51:15
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:51', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered 'Yes (Y)'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:50:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered '1'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered 'Yes (Y)'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:05', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered '4'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered 'None (1)'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:12', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '692d4874-c910-4fb8-ab91-e2cea01b45d4' User entered '16 Sep 2020 01:51'	System	16 Sep 2020 06:51:15
	System	16 Sep 2020 06:51:15

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 3'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:36:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '693708d1-73b9-4db8-8850-b2fda76335c0' User entered 'None (1)'	System	17 Sep 2020 14:37:07
	System	17 Sep 2020 14:37:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:36:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '693708d1-73b9-4db8-8850-b2fda76335c0' User entered 'No (N)'	System	17 Sep 2020 14:37:07
	System	17 Sep 2020 14:37:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:36:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '693708d1-73b9-4db8-8850-b2fda76335c0' User entered 'No (N)'	System	17 Sep 2020 14:37:07
	System	17 Sep 2020 14:37:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:36:51', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '693708d1-73b9-4db8-8850-b2fda76335c0' User entered 'None (1)'	System	17 Sep 2020 14:37:07
	System	17 Sep 2020 14:37:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:36:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '693708d1-73b9-4db8-8850-b2fda76335c0' User entered '17 Sep 2020 09:36'	System	17 Sep 2020 14:37:07
	System	17 Sep 2020 14:37:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 4'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:43', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcb48fa0-7a60-4fff-bc23-673429dfb1b0'	System	17 Sep 2020 20:51:07
User entered 'None (1)'	System	17 Sep 2020 20:51:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcb48fa0-7a60-4fff-bc23-673429dfb1b0'	System	17 Sep 2020 20:51:07
User entered 'No (N)'	System	17 Sep 2020 20:51:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:51:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcb48fa0-7a60-4fff-bc23-673429dfb1b0' User entered 'No (N)'	System	17 Sep 2020 20:51:07
	System	17 Sep 2020 20:51:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:51:03', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcb48fa0-7a60-4fff-bc23-673429dfb1b0'	System	17 Sep 2020 20:51:07
User entered 'None (1)'	System	17 Sep 2020 20:51:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:51:05', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcb48fa0-7a60-4fff-bc23-673429dfb1b0'	System	17 Sep 2020 20:51:07
User entered '17 Sep 2020 15:51'	System	17 Sep 2020 20:51:07

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 5'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5bca475a-5570-4a6c-8977-77ebe5cc7f5f' User entered 'None (1)'	System	18 Sep 2020 23:44:19
	System	18 Sep 2020 23:44:19

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:05', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5bca475a-5570-4a6c-8977-77ebe5cc7f5f' User entered 'No (N)'	System	18 Sep 2020 23:44:19
	System	18 Sep 2020 23:44:19

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:09', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5bca475a-5570-4a6c-8977-77ebe5cc7f5f' User entered 'No (N)'	System	18 Sep 2020 23:44:19
	System	18 Sep 2020 23:44:19

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:13', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5bca475a-5570-4a6c-8977-77ebe5cc7f5f' User entered 'None (1)'	System	18 Sep 2020 23:44:19
	System	18 Sep 2020 23:44:19

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5bca475a-5570-4a6c-8977-77ebe5cc7f5f' User entered '18 Sep 2020 18:44'	System	18 Sep 2020 23:44:19
	System	18 Sep 2020 23:44:19

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 6'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:53', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '320b165f-8131-459e-b7e2-25d4cb110054' User entered 'None (1)'	System	19 Sep 2020 18:29:08
	System	19 Sep 2020 18:29:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:28:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '320b165f-8131-459e-b7e2-25d4cb110054'	System	19 Sep 2020 18:29:08
User entered 'No (N)'	System	19 Sep 2020 18:29:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:01', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '320b165f-8131-459e-b7e2-25d4cb110054' User entered 'No (N)'	System	19 Sep 2020 18:29:08
	System	19 Sep 2020 18:29:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '320b165f-8131-459e-b7e2-25d4cb110054' User entered 'None (1)'	System	19 Sep 2020 18:29:08
	System	19 Sep 2020 18:29:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '320b165f-8131-459e-b7e2-25d4cb110054' User entered '19 Sep 2020 13:29'	System	19 Sep 2020 18:29:08
	System	19 Sep 2020 18:29:08

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 7'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bd39f941-918a-4a1c-9566-f364ae3afe6c' User entered 'None (1)'	System	20 Sep 2020 17:54:30
	System	20 Sep 2020 17:54:30

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bd39f941-918a-4a1c-9566-f364ae3afe6c' User entered 'No (N)'	System	20 Sep 2020 17:54:30
	System	20 Sep 2020 17:54:30

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bd39f941-918a-4a1c-9566-f364ae3afe6c' User entered 'No (N)'	System	20 Sep 2020 17:54:30
	System	20 Sep 2020 17:54:30

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bd39f941-918a-4a1c-9566-f364ae3afe6c' User entered 'None (1)'	System	20 Sep 2020 17:54:30
	System	20 Sep 2020 17:54:30

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:28', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bd39f941-918a-4a1c-9566-f364ae3afe6c' User entered '20 Sep 2020 12:54'	System	20 Sep 2020 17:54:30
	System	20 Sep 2020 17:54:30

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:12', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:18', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7' User entered 'None (0)'	System	14 Sep 2020 22:55:36
	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:27', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7'	System	14 Sep 2020 22:55:36
User entered 'No (N)'	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-14T17:55:30', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c5ce8212-0ffc-47d3-99ce-6db39a0d1ba7'	System	14 Sep 2020 22:55:36
User entered '14 Sep 2020 17:55'	System	14 Sep 2020 22:55:36

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 17:18'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 20:11'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered 'None (0)'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:13', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab'	System	15 Sep 2020 14:57:50
User entered 'Some interference with activity (2)'	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered 'Some interference with activity (2)'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered 'Some interference with activity (2)'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered 'None (0)'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab'	System	15 Sep 2020 14:57:50
User entered 'Some interference with activity not requiring medical attention (2)'	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:43', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered 'No (N)'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-15T09:57:45', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '442e7ed8-0ac2-4610-8c43-6998f09bf3ab' User entered '15 Sep 2020 09:57'	System	15 Sep 2020 14:57:50
	System	15 Sep 2020 14:57:50

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '14 Sep 2020 21:06'	System	14 Sep 2020 22:39:02
User entered '14 Sep 2020 20:43'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 2'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'None (0)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:21', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'Some interference with activity (2)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'Some interference with activity (2)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'Some interference with activity (2)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'None (0)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e'	System	16 Sep 2020 06:51:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered 'No (N)'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-16T01:51:43', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3dc8c8c0-43a0-4231-bc06-767f7619575e' User entered '16 Sep 2020 01:51'	System	16 Sep 2020 06:51:45
	System	16 Sep 2020 06:51:45

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 3'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered 'None (0)'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:37:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54'	System	17 Sep 2020 14:38:20
User entered 'Some interference with activity (2)'	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54'	System	17 Sep 2020 14:38:20
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered 'None (0)'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:09', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered 'None (0)'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:12', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered 'None (0)'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered 'No (N)'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T09:38:18', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '772b02e7-bdd7-4e59-99b5-c726fcb57a54' User entered '17 Sep 2020 09:38'	System	17 Sep 2020 14:38:20
	System	17 Sep 2020 14:38:20

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 4'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:13', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:15', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:22', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:26', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'None (0)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:29', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered 'No (N)'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-17T15:50:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a4f2df9c-fdf6-4787-b87d-49cdaeacf092'	System	17 Sep 2020 20:50:37
User entered '17 Sep 2020 15:50'	System	17 Sep 2020 20:50:37

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 5'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:28', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:31', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:34', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:44:39', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'None (0)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:56:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered 'No (N)'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-18T18:56:17', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bcdccc0b-ccd3-4634-ab85-6a0d4a4b55d6' User entered '18 Sep 2020 18:56'	System	18 Sep 2020 23:56:21
	System	18 Sep 2020 23:56:21

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 6'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:10', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:14', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:16', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:19', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:21', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'None (0)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered 'No (N)'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-19T13:29:28', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f71787c1-8698-4ac0-8e18-e5a67faae32d' User entered '19 Sep 2020 13:29'	System	19 Sep 2020 18:29:34
	System	19 Sep 2020 18:29:34

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
Data entry locked.	System	14 Sep 2020 22:02:58
User entered 'Day 7'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:31', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:39', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:54', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:54:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered 'None (0)'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

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)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:55:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63'	System	20 Sep 2020 17:55:08
User entered 'No (N)'	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-09-20T12:55:06', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '717242b7-03cd-47d4-861b-6c732ec7aa63' User entered '20 Sep 2020 12:55'	System	20 Sep 2020 17:55:08
	System	20 Sep 2020 17:55:08

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 22:02:58

US3862021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:03:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:50:56
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 22:02:58

US3862021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	23 Sep 2020 18:39:34

US3862021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '23 Sep 2020'	Chanei Henry (b) (4)	23 Sep 2020 18:39:34
	(b) (4)	

US3862021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	23 Sep 2020 18:39:34

US3862021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 18:39:34
	(b) (4)	

US3862021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	23 Sep 2020 18:39:38

US3862021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	23 Sep 2020 18:39:38

US3862021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	01 Oct 2020 18:34:44
	(b) (4)	

US3862021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '1 Oct 2020'	Chanei Henry (b) (4)	01 Oct 2020 18:34:44

US3862021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4)	01 Oct 2020 18:34:44

US3862021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Chanei Henry (b) (4)	01 Oct 2020 18:34:44
	(b) (4)	

US3862021

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Chanei Henry (b) (4)	01 Oct 2020 18:34:49
	(b) (4)	

US3862021

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	01 Oct 2020 18:34:49

US3862021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Oct 2020 22:48:01

US3862021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered '5 Oct 2020'	Carrie Kibler (b) (4)	05 Oct 2020 22:48:01

US3862021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	05 Oct 2020 22:48:01

US3862021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:48:01
	(b) (4)	

US3862021

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Oct 2020 16:31:14
	(b) (4)	

US3862021

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	12 Oct 2020 16:31:14

US3862021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 17:18:46

US3862021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '19 Oct 2020'	Trent Davis (b) (4)	19 Oct 2020 17:18:46

US3862021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[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 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Clinic (Clinic)'	Trent Davis (b) (4)	19 Oct 2020 17:18:46

US3862021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'VISIT3'	System	19 Oct 2020 17:18:46

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '19 Oct 2020'	Trent Davis (b) (4)	19 Oct 2020 17:19:31
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '11:18'	Trent Davis (b) (4)	19 Oct 2020 17:19:31
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '19 Oct 2020 11:18'	System	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '098.2' F	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Oral (Oral)'	Trent Davis (b) (4)	19 Oct 2020 17:19:31
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '073'	Trent Davis (b) (4)	19 Oct 2020 17:19:31
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'bpm'	System	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '012'	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'breaths/min'	System	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '116'	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '081'	Trent Davis (b) (4)	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered 'mmHg'	System	19 Oct 2020 17:19:31

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17

US3862021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17

US3862021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 17:19:49

US3862021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '19 Oct 2020'	Trent Davis (b) (4)	19 Oct 2020 17:19:49
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 17:20:01

US3862021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '19 Oct 2020'	Trent Davis (b) (4)	19 Oct 2020 17:20:01
	(b) (4)	

US3862021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered '11:54'	Trent Davis (b) (4)	19 Oct 2020 17:20:01

US3862021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '19 Oct 2020 11:54'	System	19 Oct 2020 17:20:01

US3862021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:32:49
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 17:20:06

US3862021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:44:17
User entered '1'	System	19 Oct 2020 17:20:06

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 64'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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)	29 Apr 2021 08:19:55
User closed query 'Per DM CLR - Requery: Response noted, however, please confirm if there are any AE that has to be recorded in relation to the response on this form. If yes, please record AE as applicable, otherwise clarify.' (Site from DM). Query 'Per DM CLR - Requery: Response noted, however, please confirm if there are any AE that has to be recorded in relation to the response on this form. If yes, please record AE as applicable, otherwise clarify.' answered with 'SE AE #01. PARTICIPANT WAS HOSPITALIZED WITH INFEROLATERAL STEMI ON 04 OCT 2020.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:52:25
User opened query 'Per DM CLR - Requery: Response noted, however, please confirm if there are any AE that has to be recorded in relation to the response on this form. If yes, please record AE as applicable, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 22:09:54
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:10:43
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:30:35
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'This incident will be clarified with subject with their upcoming day 85 phone call' (Site from DM).	Sandra Francisco (b) (4)	10 Nov 2020 23:10:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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)
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 06:32:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:30:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b'	System	17 Oct 2020 05:37:09
User entered 'Yes (Y)'	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:29:57', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b'	System	17 Oct 2020 05:37:09
User entered 'No (N)'	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:30:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b'	System	17 Oct 2020 05:37:09
User entered 'No (N)'	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:30:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b'	System	17 Oct 2020 05:37:09
User entered 'Yes (Y)'	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:30:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b'	System	17 Oct 2020 05:37:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-17T00:31:21', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'ce54dfe4-711a-4bd6-9dec-96c7b528e21b' User entered '17 Oct 2020 00:31:21'	System	17 Oct 2020 05:37:09
	System	17 Oct 2020 05:37:09

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 71'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-26T13:46:04', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0d5d74ab-bf61-4415-80f1-9b3f4b01267a' User entered 'No (N)'	System	27 Oct 2020 01:34:07
	System	27 Oct 2020 01:34:07

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-26T13:46:08', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0d5d74ab-bf61-4415-80f1-9b3f4b01267a' User entered 'No (N)'	System	27 Oct 2020 01:34:07
	System	27 Oct 2020 01:34:07

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-26T13:46:18', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '0d5d74ab-bf61-4415-80f1-9b3f4b01267a' User entered '26 Oct 2020 13:46:18'	System	27 Oct 2020 01:34:07
	System	27 Oct 2020 01:34:07

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 78'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-31T06:58:07', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3c7d070d-2e9d-4de4-8fef-16f228714b5c'	System	31 Oct 2020 11:58:20
User entered 'No (N)'	System	31 Oct 2020 11:58:20

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-31T06:58:11', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3c7d070d-2e9d-4de4-8fef-16f228714b5c'	System	31 Oct 2020 11:58:20
User entered 'No (N)'	System	31 Oct 2020 11:58:20

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-10-31T06:58:18', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3c7d070d-2e9d-4de4-8fef-16f228714b5c' User entered '31 Oct 2020 06:58:18'	System	31 Oct 2020 11:58:20
	System	31 Oct 2020 11:58:20

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered 'Day 92'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-14T00:03:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5fbfa53a-d4b3-4ccd-9e11-9bd81c2b890b' User entered 'No (N)'	System	14 Nov 2020 06:03:43
	System	14 Nov 2020 06:03:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-14T00:03:30', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5fbfa53a-d4b3-4ccd-9e11-9bd81c2b890b' User entered 'No (N)'	System	14 Nov 2020 06:03:43
	System	14 Nov 2020 06:03:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-14T00:03:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '5fbfa53a-d4b3-4ccd-9e11-9bd81c2b890b' User entered '14 Nov 2020 00:03:40'	System	14 Nov 2020 06:03:43
	System	14 Nov 2020 06:03:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:52:43

US3862021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:55
Data entry locked.	System	17 Aug 2020 20:52:43
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:52:43

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-21T04:31:18', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20caeed2-73c6-489f-a321-92c71805e65b'	System	21 Nov 2020 10:31:27
User entered 'No (N)'	System	21 Nov 2020 10:31:27

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-21T04:31:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20caeed2-73c6-489f-a321-92c71805e65b'	System	21 Nov 2020 10:31:27
User entered 'No (N)'	System	21 Nov 2020 10:31:27

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-21T04:31:23', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20caeed2-73c6-489f-a321-92c71805e65b' User entered '21 Nov 2020 04:31:23'	System	21 Nov 2020 10:31:27
	System	21 Nov 2020 10:31:27

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-26T05:41:56', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7afa07a0-db5a-4422-b0f0-00e10f1cd9ec'	System	26 Nov 2020 11:42:07
User entered 'No (N)'	System	26 Nov 2020 11:42:07

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-26T05:41:59', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7afa07a0-db5a-4422-b0f0-00e10f1cd9ec'	System	26 Nov 2020 11:42:07
User entered 'No (N)'	System	26 Nov 2020 11:42:07

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-11-26T05:42:02', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '7afa07a0-db5a-4422-b0f0-00e10f1cd9ec' User entered '26 Nov 2020 05:42:02'	System	26 Nov 2020 11:42:07
	System	26 Nov 2020 11:42:07

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-02T00:21:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a6a6c618-2819-46f8-9824-609c22bf811f'	System	02 Dec 2020 06:21:58
User entered 'No (N)'	System	02 Dec 2020 06:21:58

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-02T00:21:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a6a6c618-2819-46f8-9824-609c22bf811f'	System	02 Dec 2020 06:21:58
User entered 'No (N)'	System	02 Dec 2020 06:21:58

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-02T00:21:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'a6a6c618-2819-46f8-9824-609c22bf811f' User entered '02 Dec 2020 00:21:55'	System	02 Dec 2020 06:21:58
	System	02 Dec 2020 06:21:58

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-09T00:36:36', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8f254b59-2572-4542-a556-b7daad4967b1' User entered 'No (N)'	System	09 Dec 2020 06:36:49
	System	09 Dec 2020 06:36:49

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-09T00:36:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8f254b59-2572-4542-a556-b7daad4967b1'	System	09 Dec 2020 06:36:49
User entered 'No (N)'	System	09 Dec 2020 06:36:49

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-09T00:36:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '8f254b59-2572-4542-a556-b7daad4967b1' User entered '09 Dec 2020 00:36:47'	System	09 Dec 2020 06:36:49
	System	09 Dec 2020 06:36:49

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-16T04:12:20', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '60390e7f-42c6-4bf1-b87b-ad778afe3add' User entered 'No (N)'	System	16 Dec 2020 10:12:31
	System	16 Dec 2020 10:12:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-16T04:12:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '60390e7f-42c6-4bf1-b87b-ad778afe3add'	System	16 Dec 2020 10:12:31
User entered 'No (N)'	System	16 Dec 2020 10:12:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-16T04:12:28', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '60390e7f-42c6-4bf1-b87b-ad778afe3add' User entered '16 Dec 2020 04:12:28'	System	16 Dec 2020 10:12:31
	System	16 Dec 2020 10:12:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-23T00:02:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3730af9a-7210-4d37-91be-420fe0b4686b' User entered 'No (N)'	System	23 Dec 2020 06:02:59
	System	23 Dec 2020 06:02:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-23T00:02:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3730af9a-7210-4d37-91be-420fe0b4686b'	System	23 Dec 2020 06:02:59
User entered 'No (N)'	System	23 Dec 2020 06:02:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-23T00:02:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '3730af9a-7210-4d37-91be-420fe0b4686b' User entered '23 Dec 2020 00:02:55'	System	23 Dec 2020 06:02:59
	System	23 Dec 2020 06:02:59

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-30T00:08:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '214f8f57-9e69-4c84-89e5-e047ca3fe1b0'	System	30 Dec 2020 06:08:54
User entered 'No (N)'	System	30 Dec 2020 06:08:54

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-30T00:08:47', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '214f8f57-9e69-4c84-89e5-e047ca3fe1b0'	System	30 Dec 2020 06:08:54
User entered 'No (N)'	System	30 Dec 2020 06:08:54

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2020-12-30T00:08:51', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '214f8f57-9e69-4c84-89e5-e047ca3fe1b0' User entered '30 Dec 2020 00:08:51'	System	30 Dec 2020 06:08:54
	System	30 Dec 2020 06:08:54

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-06T20:25:52', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '312d1761-90ad-4bab-8499-cccd9e142a53'	System	07 Jan 2021 02:26:01
User entered 'No (N)'	System	07 Jan 2021 02:26:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-06T20:25:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '312d1761-90ad-4bab-8499-cccd9e142a53'	System	07 Jan 2021 02:26:01
User entered 'No (N)'	System	07 Jan 2021 02:26:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-06T20:25:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '312d1761-90ad-4bab-8499-cccd9e142a53' User entered '06 Jan 2021 20:25:58'	System	07 Jan 2021 02:26:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-13T01:30:50', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1fe2b63c-3a04-4a0f-b0f9-9b1367c672f3'	System	13 Jan 2021 07:31:01
User entered 'No (N)'	System	13 Jan 2021 07:31:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-13T01:30:55', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1fe2b63c-3a04-4a0f-b0f9-9b1367c672f3'	System	13 Jan 2021 07:31:01
User entered 'No (N)'	System	13 Jan 2021 07:31:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-13T01:30:58', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1fe2b63c-3a04-4a0f-b0f9-9b1367c672f3' User entered '13 Jan 2021 01:30:58'	System	13 Jan 2021 07:31:01
	System	13 Jan 2021 07:31:01

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-22T01:59:41', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd65077c9-aa13-4b67-a495-160207459c67'	System	22 Jan 2021 07:59:51
User entered 'No (N)'	System	22 Jan 2021 07:59:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-22T01:59:44', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd65077c9-aa13-4b67-a495-160207459c67'	System	22 Jan 2021 07:59:51
User entered 'No (N)'	System	22 Jan 2021 07:59:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-22T01:59:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'd65077c9-aa13-4b67-a495-160207459c67' User entered '22 Jan 2021 01:59:48'	System	22 Jan 2021 07:59:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-29T12:33:25', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1e1137c4-0be8-488c-9b87-5478c1e271b9'	System	29 Jan 2021 18:33:34
User entered 'No (N)'	System	29 Jan 2021 18:33:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-29T12:33:27', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1e1137c4-0be8-488c-9b87-5478c1e271b9'	System	29 Jan 2021 18:33:34
User entered 'No (N)'	System	29 Jan 2021 18:33:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-01-29T12:33:32', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1e1137c4-0be8-488c-9b87-5478c1e271b9' User entered '29 Jan 2021 12:33:32'	System	29 Jan 2021 18:33:34
	System	29 Jan 2021 18:33:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-03T02:04:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'df06a55d-dd15-43c3-b8b8-a8ac480f7d12'	System	03 Feb 2021 08:04:45
User entered 'No (N)'	System	03 Feb 2021 08:04:45

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-03T02:04:35', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'df06a55d-dd15-43c3-b8b8-a8ac480f7d12'	System	03 Feb 2021 08:04:45
User entered 'No (N)'	System	03 Feb 2021 08:04:45

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-03T02:04:38', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'df06a55d-dd15-43c3-b8b8-a8ac480f7d12' User entered '03 Feb 2021 02:04:38'	System	03 Feb 2021 08:04:45
	System	03 Feb 2021 08:04:45

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-10T00:24:30', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '130c52b2-3b3b-4be9-933a-3c07be4d7846'	System	10 Feb 2021 06:24:40
User entered 'No (N)'	System	10 Feb 2021 06:24:40

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-10T00:24:33', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '130c52b2-3b3b-4be9-933a-3c07be4d7846'	System	10 Feb 2021 06:24:40
User entered 'No (N)'	System	10 Feb 2021 06:24:40

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-10T00:24:37', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '130c52b2-3b3b-4be9-933a-3c07be4d7846'	System	10 Feb 2021 06:24:40
User entered '10 Feb 2021 00:24:37'	System	10 Feb 2021 06:24:40

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-17T00:20:40', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f38a8d79-9e15-42a2-b979-5d43fb287157'	System	17 Feb 2021 06:20:51
User entered 'No (N)'	System	17 Feb 2021 06:20:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-17T00:20:43', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f38a8d79-9e15-42a2-b979-5d43fb287157'	System	17 Feb 2021 06:20:51
User entered 'No (N)'	System	17 Feb 2021 06:20:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-17T00:20:48', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'f38a8d79-9e15-42a2-b979-5d43fb287157'	System	17 Feb 2021 06:20:51
User entered '17 Feb 2021 00:20:48'	System	17 Feb 2021 06:20:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-24T01:46:41-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e91db551-45b7-43d2-a0ba-6d0dfed7c8cc'	System	24 Feb 2021 07:46:51
User entered 'No (N)'	System	24 Feb 2021 07:46:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-24T01:46:45-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e91db551-45b7-43d2-a0ba-6d0dfed7c8cc'	System	24 Feb 2021 07:46:51
User entered 'No (N)'	System	24 Feb 2021 07:46:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-02-24T01:46:48-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'e91db551-45b7-43d2-a0ba-6d0dfed7c8cc'	System	24 Feb 2021 07:46:51
User entered '24 Feb 2021 07:46:48'	System	24 Feb 2021 07:46:51

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-03T06:29:26-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b24fb34d-ab2a-4293-8046-6da734e14b45'	System	03 Mar 2021 12:29:34
User entered 'No (N)'	System	03 Mar 2021 12:29:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-03T06:29:28-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b24fb34d-ab2a-4293-8046-6da734e14b45'	System	03 Mar 2021 12:29:34
User entered 'No (N)'	System	03 Mar 2021 12:29:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-03T06:29:31-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'b24fb34d-ab2a-4293-8046-6da734e14b45'	System	03 Mar 2021 12:29:34
User entered '03 Mar 2021 06:29:31'	System	03 Mar 2021 12:29:34

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-10T00:58:01-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bddd8de5-586b-4d3a-a57d-1d803d990a1e'	System	10 Mar 2021 06:58:13
User entered 'No (N)'	System	10 Mar 2021 06:58:13

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-10T00:58:03-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bddd8de5-586b-4d3a-a57d-1d803d990a1e'	System	10 Mar 2021 06:58:13
User entered 'No (N)'	System	10 Mar 2021 06:58:13

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-10T00:58:10-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'bddd8de5-586b-4d3a-a57d-1d803d990a1e' User entered '10 Mar 2021 00:58:10'	System	10 Mar 2021 06:58:13
	System	10 Mar 2021 06:58:13

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-17T00:03:44-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '81b1f537-6ab3-4842-b8ff-6220977e9f65'	System	17 Mar 2021 05:04:25
User entered 'No (N)'	System	17 Mar 2021 05:04:25

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-17T00:03:47-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '81b1f537-6ab3-4842-b8ff-6220977e9f65'	System	17 Mar 2021 05:04:25
User entered 'No (N)'	System	17 Mar 2021 05:04:25

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-17T00:03:50-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '81b1f537-6ab3-4842-b8ff-6220977e9f65'	System	17 Mar 2021 05:04:25
User entered '17 Mar 2021 00:03:50'	System	17 Mar 2021 05:04:25

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-24T00:14:28-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '993d5b45-1a0a-4fd3-87c5-02162fcfcfa6'	System	24 Mar 2021 05:14:38
User entered 'No (N)'	System	24 Mar 2021 05:14:38

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-24T00:14:32-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '993d5b45-1a0a-4fd3-87c5-02162fcfcfa6'	System	24 Mar 2021 05:14:38
User entered 'No (N)'	System	24 Mar 2021 05:14:38

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-24T00:14:35-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '993d5b45-1a0a-4fd3-87c5-02162fcfcfa6'	System	24 Mar 2021 05:14:38
User entered '24 Mar 2021 00:14:35'	System	24 Mar 2021 05:14:38

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-31T00:42:51-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '40fb737a-8953-4b2a-97a7-5e25c0fedf92'	System	31 Mar 2021 05:43:00
User entered 'No (N)'	System	31 Mar 2021 05:43:00

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-31T00:42:54-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '40fb737a-8953-4b2a-97a7-5e25c0fedf92'	System	31 Mar 2021 05:43:00
User entered 'No (N)'	System	31 Mar 2021 05:43:00

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-31T00:42:57-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '40fb737a-8953-4b2a-97a7-5e25c0fedf92'	System	31 Mar 2021 05:43:00
User entered '31 Mar 2021 00:42:57'	System	31 Mar 2021 05:43:00

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-07T00:53:28-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20dcf9e0-ee93-4508-bc6e-548b1e216b23'	System	07 Apr 2021 05:53:37
User entered 'No (N)'	System	07 Apr 2021 05:53:37

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-07T00:53:31-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20dcf9e0-ee93-4508-bc6e-548b1e216b23'	System	07 Apr 2021 05:53:37
User entered 'No (N)'	System	07 Apr 2021 05:53:37

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-07T00:53:33-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '20dcf9e0-ee93-4508-bc6e-548b1e216b23'	System	07 Apr 2021 05:53:37
User entered '07 Apr 2021 00:53:33'	System	07 Apr 2021 05:53:37

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-14T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c03287b3-3c58-4841-9fa4-2c8066ca308b'	System	14 Apr 2021 05:02:31
User entered 'No (N)'	System	14 Apr 2021 05:02:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-14T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c03287b3-3c58-4841-9fa4-2c8066ca308b'	System	14 Apr 2021 05:02:31
User entered 'No (N)'	System	14 Apr 2021 05:02:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-14T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: 'c03287b3-3c58-4841-9fa4-2c8066ca308b' User entered '14 Apr 2021 00:02:27'	System	14 Apr 2021 05:02:31
	System	14 Apr 2021 05:02:31

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-21T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2c4e8922-e7cd-4e93-b8a7-3dacc677b163' User entered 'No (N)'	System	21 Apr 2021 05:02:28
	System	21 Apr 2021 05:02:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-21T00:02:21-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2c4e8922-e7cd-4e93-b8a7-3dacc677b163'	System	21 Apr 2021 05:02:28
User entered 'No (N)'	System	21 Apr 2021 05:02:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-21T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '2c4e8922-e7cd-4e93-b8a7-3dacc677b163' User entered '21 Apr 2021 00:02:24'	System	21 Apr 2021 05:02:28
	System	21 Apr 2021 05:02:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-28T00:17:34-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9201372a-da16-4475-b438-3aeeb12600e7'	System	29 Apr 2021 06:13:19
User entered 'No (N)'	System	29 Apr 2021 06:13:19

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

Have you been exposed to someone with 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 (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-28T00:17:36-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9201372a-da16-4475-b438-3aeeb12600e7'	System	29 Apr 2021 06:13:19
User entered 'No (N)'	System	29 Apr 2021 06:13:19

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-04-28T00:17:39-05:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '9201372a-da16-4475-b438-3aeeb12600e7'	System	29 Apr 2021 06:13:19
User entered '28 Apr 2021 00:17:39'	System	29 Apr 2021 06:13:19

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:41:28

US3862021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:03:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:41:28
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:41:28

US3862021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 15:03:34

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)	29 Apr 2021 13:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-03T06:29:16-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1bd94da0-8b01-4891-bc4d-0f1afe6994d5'	System	03 Mar 2021 12:29:24
User entered 'No (N)'	System	03 Mar 2021 12:29:24

US3862021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 15:03:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABA286D6-DEFC-4E04-8E37-B25EA92EFE65)', Time: '2021-03-03T06:29:22-06:00', User OID: 'PatientReportedOutcome (US3862021)', ODM File OID: '1bd94da0-8b01-4891-bc4d-0f1afe6994d5' User entered '03 Mar 2021 06:29:22'	System	03 Mar 2021 12:29:24
	System	03 Mar 2021 12:29:24

US3862021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:15
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	11 Nov 2020 17:48:33

US3862021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:15
User entered '11 Nov 2020'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 17:48:33

US3862021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:15
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 17:48:33

US3862021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:15
User entered empty.	Sandra Francisco (b) (4)	11 Nov 2020 17:48:33
	(b) (4)	

US3862021

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:25:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	15 Dec 2020 15:53:35
	(b) (4)	

US3862021

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:43:06
User entered '1'	System	15 Dec 2020 15:53:35

US3862021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	23 Mar 2021 01:54:46
User entered 'No (N)'	Carrie Kibler (b) (4)	23 Mar 2021 01:53:55

US3862021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '15 Dec 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	23 Mar 2021 01:54:46
User entered empty.	Carrie Kibler (b) (4)	23 Mar 2021 01:53:55

US3862021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	23 Mar 2021 01:54:46
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	23 Mar 2021 01:53:55
	(b) (4)	

US3862021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'ONLY ONE ATTEMPT MADE. PD CREATED.' reason for change: Data Entry Error	Carrie Kibler (b) (4)	23 Mar 2021 01:54:46
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	23 Mar 2021 01:53:55
	(b) (4)	

US3862021

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:54:51

US3862021

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User entered '1'	System	11 Jan 2021 22:54:51

US3862021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:55:01

US3862021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:55:01

US3862021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:55:01

US3862021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Thea Marie Cordero (b) (4)	11 Jan 2021 22:55:01

US3862021

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:55:12

US3862021

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User entered '1'	System	11 Jan 2021 22:55:12

US3862021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 20:18:12

US3862021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 20:18:12

US3862021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 20:18:12

US3862021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 20:18:12

US3862021

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 20:18:20

US3862021

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:05
User entered '1'	System	12 Feb 2021 20:18:20

US3862021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 13:09:38

US3862021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 13:09:38

US3862021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[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 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 13:09:38

US3862021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered 'VISIT4'	System	15 Mar 2021 13:09:38

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Mar 2021'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11:13'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered '12 Mar 2021 11:13'	System	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '097.8' F	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47
	(b) (4)	

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Other (Other)'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Temporal'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '070'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered 'bpm'	System	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '016'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered 'breaths/min'	System	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '094'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered 'mmHg'	System	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
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)	04 Apr 2021 14:23:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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).	Shetel Anassi (b) (4)	30 Mar 2021 21:36:55
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).	(b) (4)	30 Mar 2021 21:36:47
User entered '057'	Shetel Anassi (b) (4)	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered 'mmHg'	System	30 Mar 2021 21:36:47

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16

US3862021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:03:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16

US3862021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 13:09:50

US3862021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:03:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 13:09:50

US3862021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 13:10:27

US3862021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 13:10:27

US3862021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11:31'	(b) (4), (b) (6)	15 Mar 2021 13:10:27

US3862021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered '12 Mar 2021 11:31'	System	15 Mar 2021 13:10:27

US3862021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 13:10:34

US3862021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:15:16
User entered '1'	System	15 Mar 2021 13:10:34

US3862021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:27
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Apr 2021 21:15:22
	(b) (4)	

US3862021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:27
User entered '12 Apr 2021'	Shetel Anassi (b) (4)	12 Apr 2021 21:15:22
	(b) (4)	

US3862021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:27
User entered 'Contact Not Made (CONTACT NOT MADE)'	Shetel Anassi (b) (4)	12 Apr 2021 21:15:22

US3862021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:03:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:27
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	12 Apr 2021 21:15:39
User entered 'Unable to reach participant.' reason for change: Data Entry Error	Shetel Anassi (b) (4)	12 Apr 2021 21:15:39
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	(b) (4)	12 Apr 2021 21:15:22
User entered empty.	System	12 Apr 2021 21:15:22
	Shetel Anassi (b) (4)	12 Apr 2021 21:15:22
	(b) (4)	

US3862021

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:40:27
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	12 Apr 2021 21:15:47
	(b) (4)	

US3862021

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:03:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 21:15:47

US3862021

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

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	11 Jan 2021 21:11:34
	(b) (4)	

US3862021

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

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Carrie Kibler (b) (4)	11 Jan 2021 21:11:34

US3862021

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

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	11 Jan 2021 21:11:34
	(b) (4)	

US3862021

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

Form: Visit Date

Generated On: 11 Jun 2021 15:03:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:11:34

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:04:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:25:34

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 20:11:35
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'UPDATED IN EDC' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:05:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 22:04:54
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:02:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:25:34

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03
	(b) (4)	

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03
	(b) (4)	

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:30:26
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03
	(b) (4)	

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:30:26
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03
	(b) (4)	

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	11 Jan 2021 21:12:03

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User entered empty.	System	11 Jan 2021 21:12:03

US3862021

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

Form: Unblinding

Generated On: 11 Jun 2021 15:03:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User entered empty.	System	11 Jan 2021 21:12:03

US3862021

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:51:31

US3862021

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:51:31

US3862021

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '13:25'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:51:31

US3862021

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:03:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User entered '11 Jan 2021 13:25'	System	11 Jan 2021 22:51:31

US3862021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:03:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:51:45

US3862021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:03:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '11 Jan 2021'	Thea Marie Cordero (b) (4)	11 Jan 2021 22:51:45

US3862021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:03:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '13:21' reason for change: New Information	Thea Marie Cordero	11 Jan 2021 22:52:04
User entered '13:25'	(b) (4)	
	Thea Marie Cordero	11 Jan 2021 22:51:45
	(b) (4)	

US3862021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:03:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:07:00
User entered '11 Jan 2021 13:21'	System	11 Jan 2021 22:52:04
User entered '11 Jan 2021 13:25'	System	11 Jan 2021 22:51:45

US3862021

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 15:03:34

[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 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:15:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:47:47

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:59
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:26
User entered	System	06 Oct 2020 14:38:21
'USA-US121-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	06 Oct 2020 14:38:21

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
User closed query 'Medical records state dx as Inferolateral STEMI. Please consider updating EDC. (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:40:07
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Inferolateral myocardial infarction - version MedDRA\23.0.	(b) (4), (b) (6) Cordero Import (b) (4) (b) (4)	06 Nov 2020 14:40:03 31 Oct 2020 20:40:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Cordero Import (b) (4) (b) (4)	31 Oct 2020 20:40:23
Data point term sent to Coder	System	30 Oct 2020 21:48:00
Query 'Medical records state dx as Inferolateral STEMI. Please consider updating EDC. ' answered with 'Updated and changed' (Site from CRA). DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:39
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:30
User entered 'Inferolateral STEMI' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:30
User opened query 'Medical records state dx as Inferolateral STEMI. Please consider updating EDC. (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Oct 2020 18:27:30 14 Oct 2020 21:30:02
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Cordero Import (b) (4) (b) (4)	05 Oct 2020 22:58:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Cordero Import (b) (4) (b) (4)	05 Oct 2020 22:58:26
Data point term sent to Coder	System	05 Oct 2020 22:57:56
User entered 'myocardial infarction'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:30:09
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:30:12
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:30:14
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:18:26
DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:30
User entered '4 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:30
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:30:17
User entered '3 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:22:17
User closed query 'Per narrative pages in source, symptoms began at midnight. Please review and confirm start time.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:11:01
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 09:19:53
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Updated and changed' (Site from System).	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:52
Query 'Per narrative pages in source, symptoms began at midnight. Please review and confirm start time.' answered with 'Updated and changed' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:47
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Oct 2020 21:47:30
User entered '00:45' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:47:30
User opened query 'Per narrative pages in source, symptoms began at midnight. Please review and confirm start time.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 21:34:41
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Oct 2020 21:40:28
User entered empty; reason for change Data Entry Error	Coni Cheesman (b) (4)	06 Oct 2020 21:40:28
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Oct 2020 21:32:17
User entered '00:00' reason for change: Data Entry Error	Coni Cheesman (b) (4)	06 Oct 2020 21:32:17
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Oct 2020 18:05:57
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 18:05:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Oct 2020 22:57:54
User entered '12:00'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Oct 2020 00:45'	System	30 Oct 2020 21:47:30
User entered empty.	System	06 Oct 2020 21:40:28
User entered '3 Oct 2020 00:00'	System	06 Oct 2020 21:32:17
User entered empty.	System	06 Oct 2020 18:05:57
User entered '3 Oct 2020 12:00'	System	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:34:49
User entered 'No (N)' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 21:34:52
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Oct 2020 21:37:06
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Oct 2020 21:37:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Oct 2020 21:34:37
User entered '7 Oct 2020' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:35:34
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:35:36
User entered 'Grade 4 (Grade 4)'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:35:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:35:50
User entered '0'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:35:51
User entered '1'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:35:53
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 08:15:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Date of admission-03Oct2020, no additional information available at this time' (Site from System).	Coni Cheesman (b) (4)	06 Oct 2020 21:45:11
Comment added 'Date of admission 03 Oct 2020. No additional information available at this time'.	Coni Cheesman (b) (4)	06 Oct 2020 21:44:07
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	05 Oct 2020 22:57:54
User entered '1'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 19:19:19
User closed query 'Please confirm date of hospital admission. Per his medical records show admission as of 04Oct2020. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:11:10
Query 'Please confirm date of hospital admission. Per his medical records show admission as of 04Oct2020. ' answered with 'Updated and changed' (Site from CRA).	Sandra Francisco (b) (4)	30 Oct 2020 21:48:04
	(b) (4)	
DataPoint Un-verified.	Sandra Francisco (b) (4)	30 Oct 2020 21:47:30
	(b) (4)	
User entered '4 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	30 Oct 2020 21:47:30
	(b) (4)	
User opened query 'Please confirm date of hospital admission. Per his medical records show admission as of 04Oct2020. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:41:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:38:30
User entered '3 Oct 2020'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
User closed query 'Please confirm date of discharge. Per subjects medical records, subject was discharged on 06Oct2020. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:04:42
Query 'Please confirm date of discharge. Per subjects medical records, subject was discharged on 06Oct2020. ' answered with 'Date of discharge is correct.' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 22:02:19
User opened query 'Please confirm date of discharge. Per subjects medical records, subject was discharged on 06Oct2020. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:42:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:38:32
User entered '7 Oct 2020' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:38:57
User entered 'Yes (Y)' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:38:59
User entered '2' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:39:01
User entered '0'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:39:03
User entered '0'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:39:04
User entered '0'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:39:29
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:04:35
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Causality not related to investigational product' (Site from Safety).	Coni Cheesman (b) (4)	06 Oct 2020 21:46:06
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 21:32:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 21:32:17
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Coni Cheesman (b) (4)	06 Oct 2020 21:32:17
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 17:51:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 22:57:54
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 21:39:31
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 21:32:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 21:32:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	06 Oct 2020 21:32:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 22:57:54
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 21:39:36
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 21:32:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 21:32:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Coni Cheesman (b) (4)	06 Oct 2020 21:32:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 22:57:54
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 21:39:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Oct 2020 21:34:37
Comment added 'Subject has not responded to phone calls on 06 oct 2020. More information will be obtained and submitted as soon as possible.'	Coni Cheesman (b) (4)	06 Oct 2020 21:39:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Oct 2020 22:57:54
User entered '0'	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
User closed query 'Per CDM re-query: Site response is noted. Please update conmeds once medical records are available. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:58:56
Query 'Per CDM re-query: Site response is noted. Please update conmeds once medical records are available. Thank you.' answered with 'con meds have been updated. EDC reflects source' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	23 Nov 2020 23:22:49
User opened query 'Per CDM re-query: Site response is noted. Please update conmeds once medical records are available. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:29:03
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.	(b) (4), (b) (6)	18 Nov 2020 15:29:03
' (Site from DM).		
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.	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 23:04:00
' answered with 'pending medical records' (Site from DM).		
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.	(b) (4), (b) (6)	07 Nov 2020 10:15:47
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:39:41
User entered '1' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User entered '0'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 19:22:08
User closed query 'Per source, concomitant procedures were done. Please update.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:11:23
Query 'Per source, concomitant procedures were done. Please update.' answered with 'Updated and changed. Concomitant Procedures will be updated.' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:48:53
User entered '1' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 21:48:44
User opened query 'Per source, concomitant procedures were done. Please update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 21:40:22
User entered '0'	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:39:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:37:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:34:37
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 18:06:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 18:06:20
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 18:06:20
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 22:57:54
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Oct 2020 22:57:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:39:58
User entered empty.	Carrie Kibler (b) (4)	05 Oct 2020 22:57:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'AT MIDNIGHT ON OCTOBER 3, PARTICIPANT WAS EXPERIENCING CHEST PAIN THAT WAS RADIATING TO HIS ARM, DIAPHORESIS, AND BLURRY VISION. HE WENT STRAIGHT TO THE EMERGENCY ROOM. PENDING MEDICAL RELEASE INFORMATION FROM HOSPITAL. 06OCT2020 SAE SUMMARY: AS ABOVE. PAST MEDICAL HISTORY OBTAINED DURING SCREENING AND ENROLLMENT INCLUDED HISTORY OF A ROUTINE STRESS TEST IN JUN 2019 WITH A POSITIVE FINDING. A FOLLOW UP CARDIAC CATHETERIZATION WAS DONE. THERE WAS NO SURGICAL INTERVENTION. NO ADDITIONAL PERTINENT MEDICAL HISTORY WAS PROVIDED. 10OCT2020 SAE UPDATE #1: PER PHONE INTERVIEW WITH SUBJECT. SUBJECT REPORTS TO HAVE BEEN DOING WELL WITH ROUTINE CARDIOLOGY VISIT 1 WEEK PRIOR TO EVENT. WALKED 4.5MILES THAT DAY WITHOUT PAIN OR SHORTNESS OF BREATH. REPORTS TO HAVE UNDERGONE CARDIAC CATHETERIZATION WITH FINDING OF RUPTURED PLAQUE AND PLACEMENT OF 3 STENTS. MEDICATIONS WERE ADJUSTED. NO SIGNS/SYMPTOMS OF COVID-19, AND A SCREENING TEST ON ADMISSION WAS NEGATIVE. AFTER DISCHARGE, SUBJECT FOLLOWED UP WITH CARDIOLOGIST ON 09 OCT 2020, AND PLANS TO RETURN IN 2 WEEKS FOR STRESS TEST. RELEASE OF INFORMATION REQUESTED FOR PERMISSION TO OBTAIN MEDICAL RECORDS FROM HOSPITAL AND CARDIOLOGISTS.' (WR#5445128)	System	11 Jun 2021 14:45:08
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:11:26
User closed query 'PV Query: Medical records were not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:09:12
PRODUCTION RELEASE (v12.003 EAB) (1725)		1797 of 2819

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Medical records were not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' answered with 'Attempts were made to securely send redacted medical records the provided e-mail above on 24NOV2020, 14DEC2020, and 31JAN2021. Please keep an eye for these documents via e-mail and fax. ' (Site from Safety).	Sandra Francisco (b) (4)	30 Jan 2021 19:23:32
User opened query 'PV Query: Medical records were not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:03:13
User closed query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:33:18
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:33:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results during time of hospitalization. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:33:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..Please leave query open until information is available. ' answered with 'All available medical records have been redacted and securely e-mailed to Safety_Moderna@iqvia.com.' (Site from Safety).	Sandra Francisco (b) (4)	24 Nov 2020 17:21:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available. ' answered with 'All available medical records have been redacted and securely e-mailed to Safety_Moderna@iqvia.com.' (Site from Safety).	Sandra Francisco (b) (4)	24 Nov 2020 17:21:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results during time of hospitalization. Please include units and reference ranges if applicable. Please leave query open until information is available. ' answered with 'All available medical records have been redacted and securely e-mailed to Safety_Moderna@iqvia.com.' (Site from Safety).	Sandra Francisco (b) (4)	24 Nov 2020 17:21:10
User opened query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:25:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:25:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results during time of hospitalization. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:25:19
User closed query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:50:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:50:18
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:50:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:22:05
Query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..' answered with 'pending medical records' (Site from Safety).	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 23:04:26

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records' (Site from Safety).	Sandra Francisco (b) (4)	10 Nov 2020 23:04:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'pending medical records' (Site from Safety).	Sandra Francisco (b) (4)	10 Nov 2020 23:04:07
User opened query 'PV Query: Please provide treatment medications given during the time of the event/hospitalization 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 confirm..'. (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 12:43:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.'. (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:44:47
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.'. (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:44:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:57:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 22:57:54

US3862021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:03:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Oct 2020 21:34:37

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Adrenal cortex tests, PT: Cortisol decreased, LLT: Cortisol low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:00:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:00:17
Data point term sent to Coder	System	25 Mar 2021 13:29:28
User entered 'LOW CORTISOL LEVEL'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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)'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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)'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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
User entered 'No (N)'	(b) (4)	25 Mar 2021 13:29:14
	(b) (4), (b) (6)	

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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 '04 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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)'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered '0'	(b) (4)	25 Mar 2021 13:29:14
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[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'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 13:29:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 13:29:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:14
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 13:29:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 13:29:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:14
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 13:29:44
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 13:29:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 13:29:14
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

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.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:03:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 13:29:14

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
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)	08 Apr 2021 22:33:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 22:33:49
Data point term sent to Coder	System	08 Apr 2021 22:33:06
User entered 'UNCONTROLLED TYPE 2 DIABETES MELLITUS'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '14 Dec 2020'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 22:32:11

US3862021

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:03:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 22:32:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 15:03:34

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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:04:52
User closed query 'Per subjects medical records, shows multiple ConMeds were given and or taken. Please update source and EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:04:50
Query 'Per subjects medical records, shows multiple ConMeds were given and or taken. Please update source and EDC accordingly. ' answered with 'completed' (Site from CRA).	Sandra Francisco (b) (4)	10 Nov 2020 23:10:40
User opened query 'Per subjects medical records, shows multiple ConMeds were given and or taken. Please update source and EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 18:46:30
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 18:45:20
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:44:35

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 19:55:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:54:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:31:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:31:20
Data point term sent to Coder	System	17 Aug 2020 22:48:16
User entered 'NOVOLOG 70/30'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:54:58
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'DIABETES MELLITUS TYPE 2'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'IU (IU)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:19:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'twice daily (BID)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Signature has been broken.	Carrie Kibler (b) (4)	08 Apr 2021 17:15:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Subcutaneous (SUBCUTANEOUS)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:32:41
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 22:48:15
User entered 'UN UNK 2016'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:48:57
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:48:57
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User entered '2'	System	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User entered '1'	System	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:30
User entered '804 (804)'	System	17 Aug 2020 22:48:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:50:22
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 22:50:22
Data point term sent to Coder User entered 'NORVASC'	System Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:49:20 17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'HYPERTENSION'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '5'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:33:02
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 22:49:17
User entered 'UN Jun 2019'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 22:45:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '05 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:45:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User entered '1'	System	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User entered '1'	System	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:39
User entered '804 (804)'	System	17 Aug 2020 22:49:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 22:52:25
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 22:52:25
Data point term sent to Coder	System	17 Aug 2020 22:51:23
User entered 'SYNTHROID'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'HYPOTHROIDISM'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '200'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'ug (ug)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:33:12
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 22:51:04
User entered 'UN UNK 2008'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 20:19:09
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 20:19:09
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User entered '1'	System	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User entered '1'	System	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:43
User entered '804 (804)'	System	17 Aug 2020 22:51:04

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:41:43
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4) (b) (4)	16 Nov 2020 15:40:23 16 Nov 2020 15:39:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:57:48
Data point term sent to Coder Coding entries removed.	System Coni Cheesman (b) (4)	10 Oct 2020 21:42:37 10 Oct 2020 21:42:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:04:22
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 23:04:22
Data point term sent to Coder	System	17 Aug 2020 23:03:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'TOPROL'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Please confirm, as this medication is prescribed for hypertension.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 20:16:56
Query 'Please confirm, as this medication is prescribed for hypertension.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:44:50
User entered 'HYPERTension' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 15:39:43
User opened query 'Please confirm, as this medication is prescribed for hypertension.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:56:32
User entered 'HYPERTHYROIDISM' reason for change: Data Entry Error	Coni Cheesman (b) (4)	10 Oct 2020 21:42:24
User entered 'HYPERTENSION'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '100'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'twice daily (BID)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:45:40
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Subject began medication for hyperthyroidism, ongoing use for hypertension.' (Site from DM).	Coni Cheesman (b) (4)	10 Oct 2020 21:43:23
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:42:23
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 00:33:21
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 23:02:40
User entered 'UN UNK 2008'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	17 Dec 2020 17:37:08
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4)	
' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:09:18
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	05 Nov 2020 18:08:12
' (Site from DM).		
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '05 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	17 Dec 2020 17:37:08
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User entered '2'	System	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User entered '1'	System	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:15:47
User entered '804 (804)'	System	17 Aug 2020 23:02:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 23:04:22
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 23:04:22
Data point term sent to Coder	System	17 Aug 2020 23:03:38
User entered 'FLOMAX'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0.4'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:33:33
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 23:03:33
User entered 'UN UNK 2017'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 23:03:33

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE SODIUM, PRODUCTSYNONYM: CYTOMEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 18:05:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 18:05:37
Data point term sent to Coder Coding entries removed.	System Sandra Francisco (b) (4)	11 Nov 2020 17:49:45 11 Nov 2020 17:49:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE SODIUM, PRODUCTSYNONYM: CYTOMEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:06:24
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 23:06:24
Data point term sent to Coder User entered 'CYTOMEL'	System Carrie Kibler (b) (4)	17 Aug 2020 23:05:43 17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Hypothyroidism' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	11 Nov 2020 17:49:19
User entered 'HYPORTHYROIDISM'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '5'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'ug (ug)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'other (OTHER)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Monday-Friday one time each of those days'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:33:42
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 23:05:30
User entered 'un UNK 2017'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:05:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE SODIUM, PRODUCTSYNONYM: CYTOMEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:08:26
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 23:08:26
Data point term sent to Coder	System	17 Aug 2020 23:06:43
User entered 'cytomel'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hypothyroidism'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	17 Aug 2020 23:06:59
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	17 Aug 2020 23:06:23
User entered 'ug (ug)'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:06:59
User entered 'Saturday and Sunday one time each of those days'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'other (OTHER)'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:06:59
User entered 'SATURDAY AND SUNDAY ONE TIME EACH OF THOSE DAYS' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Aug 2020 23:06:59
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	17 Aug 2020 23:06:23
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:33:53
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 23:06:23
User entered 'un UNK 2017'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:06:23

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:08:27
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 23:08:27
Data point term sent to Coder User entered 'zetia'	System Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:07:47 17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hyperlipidemia'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:34:05
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 23:07:40
User entered 'un UNK 2016'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 20:19:45
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Feb 2021 20:19:45
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User entered '1'	System	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User entered '1'	System	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:15
User entered '804 (804)'	System	17 Aug 2020 23:07:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:10:13
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 23:10:13
Data point term sent to Coder	System	17 Aug 2020 23:08:48
User entered 'vitamin d'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:26:35
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4)	14 Dec 2020 16:35:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Dec 2020 16:35:02
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:38:09
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:28:02
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.	Shetel Anassi (b) (4) (b) (4)	03 Nov 2020 18:55:48
' answered with 'Data corrected' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:03:25
User entered 'vitamin d deficiency'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '50,000'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'IU (IU)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'other (OTHER)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'every ten days'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:34:17
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 23:08:41
User entered 'un UNK 2015'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:30:08
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '06 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:33:49
User entered '07 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:30:08
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User entered empty.	System	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User entered empty.	System	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:16:36
User entered empty.	System	17 Aug 2020 23:08:41

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;OLMESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:30:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:30:16
Data point term sent to Coder	System	17 Aug 2020 23:09:49
User entered 'olmesartan hydrochlorothiazide'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hypertension'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '40/25'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:34:26
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 23:09:26
User entered 'un UNK 2020'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 23:09:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE, PRODUCTSYNONYM: IMDUR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:12:15
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 23:12:15
Data point term sent to Coder User entered 'imdur'	System Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:10:49 17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'coronary artery disease'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '30'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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 00:34:35
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 23:10:01
User entered 'un UNK 2019'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:49:49
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '04 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:49:49
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User entered '1'	System	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User entered '1'	System	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:10
User entered '804 (804)'	System	17 Aug 2020 23:10:01

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Aug 2020 23:12:15
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 23:12:15
Data point term sent to Coder	System	17 Aug 2020 23:10:50
User entered 'aspirin'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'coronary artery disease'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '325'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:09:05
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Data is corrcet' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	10 Nov 2020 17:40:21
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:41:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 00:34:44
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 23:10:30
User entered 'un UNK 2010'	Carrie Kibler (b) (4) (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:50:34
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '03 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	11 Nov 2020 17:50:34
User entered empty.	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User entered '1'	System	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User entered '1'	System	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:14
User entered '804 (804)'	System	17 Aug 2020 23:10:30

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:30:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 17:30:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 19:04:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 19:04:37
Data point term sent to Coder User entered 'Benadryl'	System	23 Sep 2020 19:03:41
	Chanei Henry (b) (4)	23 Sep 2020 19:02:43
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE SWELLING is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE SWELLING did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:33:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE SWELLING is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE SWELLING did not meet the AE reporting criteria. ' answered with 'This did not meet AE reporting criteria but this is a solicited adverse reaction. ' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:42:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '25'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:02:43
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '14 Sep 2020'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '15 Sep 2020'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Chanei Henry (b) (4)	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User entered '1'	System	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User entered '1'	System	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:18
User entered '804 (804)'	System	23 Sep 2020 19:02:43

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:05:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 19:05:39
Data point term sent to Coder	System	23 Sep 2020 19:04:43
Data point term sent to Coder	System	23 Sep 2020 19:03:41
User entered 'Ibuprofen'	Chanei Henry (b) (4) (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication of FEVER. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:09:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:09:32
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication of FEVER. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' answered with 'did not meet the AE reporting criteria, ed diary error.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	10 Nov 2020 17:38:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'did not meet the AE reporting criteria' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	10 Nov 2020 17:38:24
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication of FEVER. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:35:58
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:35:46
User entered 'FEVER and injection site pain' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	23 Sep 2020 19:04:09
User entered 'fever'	Chanei Henry (b) (4) (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '600'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'twice daily (BID)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Chanei Henry (b) (4)	23 Sep 2020 19:03:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '15 Sep 2020'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '16 Sep 2020'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Chanei Henry (b) (4)	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User entered '2'	System	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User entered '1'	System	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:22
User entered '804 (804)'	System	23 Sep 2020 19:03:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User closed query 'Per DM CLR: Con Med CARDIZEM was added/changed on 04 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:55:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Query 'Per DM CLR: Con Med CARDIZEM was added/changed on 04 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Change in medication was performed at the discretion of the cardiologist to address recovered Inferolateral STEMI (see AE#01) on 04 OCT 2020. Cardiazem 240 mg QD manages better both conditions, Hypertension and Status Post Inferolateral STEMI ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:42:43
User opened query 'Per DM CLR: Con Med CARDIZEM was added/changed on 04 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 21:31:25
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)	24 Dec 2020 19:14:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 19:14:28
PRODUCTION RELEASE (v12.003 EAB) (1725)		2130 of 2819

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Dec 2020 19:13:17
DataPoint Un-verified.	Carrie Kibler (b) (4)	24 Dec 2020 19:12:51
	(b) (4)	
Coding entries removed.	Carrie Kibler (b) (4)	24 Dec 2020 19:12:51
	(b) (4)	
User entered 'LISiNOPRIL' reason for change: Data	Carrie Kibler (b) (4)	24 Dec 2020 19:12:51
Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:40
User coded data point as ATC:	Coder Import (b) (4)	09 Nov 2020 20:51:36
CARDIOVASCULAR SYSTEM, ATC: AGENTS	(b) (4)	
ACTING ON THE RENIN-ANGIOTENSIN		
SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:		
ACE INHIBITORS, PLAIN, PRODUCT:		
LISINOPRIL - version		
WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Nov 2020 20:51:36
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	09 Nov 2020 20:50:47
User entered 'lisinopril'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:42
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:45
User entered '5'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:48
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:51
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:52
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:55
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:56
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:00:59
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:01
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:03
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:05
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:08
User entered '17 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:01:09
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:50:40
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User entered '1'	System	09 Nov 2020 20:50:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User entered '1'	System	09 Nov 2020 20:50:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:26
User entered '804 (804)'	System	09 Nov 2020 20:50:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:16:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:16:38
Data point term sent to Coder	System	09 Nov 2020 23:15:24
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:15:07
User entered 'carvedilol' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:15:07
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:14:24
Data point term sent to Coder	System	09 Nov 2020 22:37:54
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:37:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:52:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:52:36
Data point term sent to Coder	System	09 Nov 2020 20:51:48
User entered 'coreg'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:16
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:19
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered '6.25'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:23
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:27
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:29
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'twice daily (BID)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:32
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:37
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:03:55
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:14
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:16
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:20
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered '17 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:04:21
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	09 Nov 2020 22:37:11
User entered '2'	System	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
	(b) (4)	
User entered '1'	System	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:30
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 22:37:11
	(b) (4)	
User entered '804 (804)'	System	09 Nov 2020 20:51:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:32:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:32:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:17:38
Data point term sent to Coder Coding entries removed.	System Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:16:25 09 Nov 2020 23:16:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:14:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:14:38
Data point term sent to Coder	System	09 Nov 2020 23:14:24

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
Data point term sent to Coder	System	09 Nov 2020 22:37:53
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 20:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 20:53:36
Data point term sent to Coder	System	09 Nov 2020 20:52:49
User entered 'brilinta'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:54
User entered 'Yes (Y)' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 23:16:00
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:55
User entered 'cardiovascular event prevention' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 23:16:00
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'coronary artery disease'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:32
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered '90'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:34
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:35
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:37
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'twice daily (BID)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:38
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:47
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:49
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:54
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:55
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:57
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:53:59
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:54:01
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 22:37:18
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:37:18
User entered '2'	System		09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:37:18
User entered '1'	System		09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:17
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:37:18
User entered '804 (804)'	System		09 Nov 2020 20:51:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Review if this is a duplicate, and if so, remove duplicate Con Med. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:16:34
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Review if this is a duplicate, and if so, remove duplicate Con Med. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:38:14
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4. Review if this is a duplicate, and if so, remove duplicate Con Med. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:47:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:14:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:14:37
Data point term sent to Coder	System	09 Nov 2020 23:14:23
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:13:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:53:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Nov 2020 20:53:38
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	09 Nov 2020 20:52:52
User entered 'toprol'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered '100'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'twice daily (BID)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '17 Oct 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	17 Dec 2020 17:38:08
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	09 Nov 2020 23:13:55
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:13:55
User entered '2'	System		09 Nov 2020 20:52:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:13:55
User entered '1'	System		09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:14:02
DataPoint inactivated with code reason code Data not required.	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 23:13:55
User entered '804 (804)'	System		09 Nov 2020 20:52:42

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:18:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:18:35
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	19 Apr 2021 19:17:52 19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 2 (UN JUN 2019 - 05 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:41:06
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Comment added 'START DATES HAD BEEN UPDATED AS PER SOURCE DOCUMENT'.	(b) (4), (b) (6)	05 Apr 2021 22:56:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 22:56:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Apr 2021 22:56:40
Data point term sent to Coder	(b) (4)	
DataPoint activated with code reason code Data required.	System	05 Apr 2021 22:56:15
Data point term sent to Coder	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.		
	System	05 Apr 2021 22:51:09
	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 2 (UN JUN 2019 - 05 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'THIS IS A DUPLICATE. IT WILL BE INACTIVATED AS THE CCM' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 22:49:54
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM# 2 (UN JUN 2019 - 05 OCT 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:17:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 20:54:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 20:53:53
User entered 'norvasc'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '5'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered '17 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 22:56:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'UN Jun 2019' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 21:53:02
User entered '17 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 22:56:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 21:51:57
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 22:56:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Mar 2021 21:53:02
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	22 Mar 2021 21:51:57
User entered '05 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 21:51:57
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User entered '1'	System	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User entered '1'	System	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	19 Apr 2021 19:17:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	19 Apr 2021 19:17:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Apr 2021 22:55:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Apr 2021 22:50:18
User entered '804 (804)'	System	09 Nov 2020 20:53:16

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:56:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 20:56:36
Data point term sent to Coder	System	09 Nov 2020 20:55:56
User entered 'praluent'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hyperlipidemia'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '150'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once every two weeks'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '16 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:55:22

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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)	17 Nov 2020 06:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:35:53
Data point term sent to Coder	System	16 Nov 2020 15:50:31
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 15:50:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:57:03
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)	10 Nov 2020 03:57:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:57:41
Data point term sent to Coder	System	09 Nov 2020 21:42:22
Data point term sent to Coder	System	09 Nov 2020 21:33:07
User entered 'fentanyl'	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:57:04
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:06:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 16:05:59
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:05:57
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:29:04
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:50:36
User entered 'INFEROLATERAL STEMI' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 15:50:30
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:57:47
User entered 'chest pain'	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:06:01
User closed query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:03:49
Query 'Per CDM: Site response is noted. Please add data for dose per administration.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 22:57:25
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 22:57:14
User entered 'unk' reason for change: Data Entry Error	Sandra Francisco (b) (4)	23 Nov 2020 22:57:14
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:28:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:54:14
User opened query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:54:10
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:03:51
Query 'Per CDM: Site response is noted. Please add data for dose unit.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 22:57:46
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:27:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:54:28
User opened query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:54:26
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:41:09
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:27:57
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:33
User closed query 'Per source, frequency was unknown. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:41:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Query 'Per source, frequency was unknown. Please update.' answered with 'updated EDC to reflect source documentation' (Site from CRA).	Sandra Francisco (b) (4)	12 Mar 2021 16:24:45
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	12 Mar 2021 16:24:35
User opened query 'Per source, frequency was unknown. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:07:29
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:41:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:41:26
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:41:26
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:12
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:41:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:41:41
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:21
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Nov 2020 21:41:26
User entered '04 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:41:26
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:22
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:23
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:41:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:41:26
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:41:26
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:32:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:25
User entered '04 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:41:26
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:26:26
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:32:58
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User entered empty.	System	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User entered empty.	System	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:17:53
User entered empty.	System	09 Nov 2020 21:32:58

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:15
Data point term sent to Coder	System	23 Nov 2020 23:00:32
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	23 Nov 2020 22:59:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:09:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:09:42
Data point term sent to Coder	System	09 Nov 2020 21:35:09
User entered 'heparin'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:20
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:07:46
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 22:59:38
User entered 'inferolateral STEMI' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 22:59:38
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:04
User entered 'during PCI'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:58:25
User entered '80'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:29:52
User closed query 'Per source, unit is units/kg. Please update.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:29:30
Query 'Per source, unit is units/kg. Please update.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:51:53
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 15:51:45
User opened query 'Per source, unit is units/kg. Please update.' (Site from CRA).	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 21:00:46
	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:44
User closed query 'Per source, unit is units/kg. Please include the "per kg" notation as well.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:24:42
Query 'Per source, unit is units/kg. Please include the "per kg" notation as well.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	17 Nov 2020 21:56:52
User entered 'UNITS per Kg' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 21:56:47
User opened query 'Per source, unit is units/kg. Please include the "per kg" notation as well.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:29:50
User entered 'units' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 15:51:45
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:18
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:20
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:22
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:23
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:28:45
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:26
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:27
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:29
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:10
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User entered empty.	System	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User entered empty.	System	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:01
User entered empty.	System	09 Nov 2020 21:34:10

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPTIFIBATIDE, PRODUCTSYNONYM: INTEGRILIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:53:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:53:45
Data point term sent to Coder	System	16 Nov 2020 15:52:38
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPTIFIBATIDE, PRODUCTSYNONYM: INTEGRILIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:36:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:36:37
Data point term sent to Coder	System	09 Nov 2020 21:35:10
User entered 'integrilin'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:47
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:14:55
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:30:00
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:52:32
User entered 'inferolateral STEMI' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 15:52:26
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:02:17
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:01:53
User entered 'during PCI'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:54
User closed query 'Per source, dose is unknown. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:41:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Query 'Per source, dose is unknown. Please update.' answered with 'updated EDC to reflect original source documentation' (Site from CRA).	Sandra Francisco (b) (4)	12 Mar 2021 16:25:50
User entered 'unknown' reason for change: Data Entry Error	Sandra Francisco (b) (4)	12 Mar 2021 16:25:33
User opened query 'Per source, dose is unknown. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 16:14:50
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:44:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 17:44:39
User entered '20-100' reason for change: Data Entry Error	Shetel Anassi (b) (4)	10 Nov 2020 17:44:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:34:56
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:52:51
Query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. ' answered with 'Updated EDC "Other as Unknown" to answer query. No changes in source necessary. ' (Site from DM).	Sandra Francisco (b) (4)	22 Mar 2021 18:09:40
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	22 Mar 2021 18:09:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 08:04:09
User opened query 'Per CDM: Per CCG's Dose Unit should be "UNK" if data is not available. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:04:07
Query 'Data is required. Please complete.' answered with 'updated EDC to reflect original source documentation' (Site from System).	Sandra Francisco (b) (4)	12 Mar 2021 16:25:59
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 16:25:33
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	12 Mar 2021 16:25:33
User entered 'mg (mg)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	10 Nov 2020 17:44:39
User entered 'Other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'unknown' reason for change: Data Entry Error	Sandra Francisco (b) (4)	22 Mar 2021 18:09:15
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	10 Nov 2020 17:44:39
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:34:56
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:34
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:36
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:37
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:39
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:40
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:42
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:43
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:45
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:02:46
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User entered empty.	System	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User entered empty.	System	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:05
User entered empty.	System	09 Nov 2020 21:34:56

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 11:46:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	19 Nov 2020 11:46:21
Data point term sent to Coder	System	16 Nov 2020 15:53:40
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 15:52:58
DataPoint Verified.	(b) (4)	11 Nov 2020 21:04:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:37:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	10 Nov 2020 03:37:42
Data point term sent to Coder	System	09 Nov 2020 21:36:14
User entered 'aspirin'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:21
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:35
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:30:08
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:53:04
User entered 'INFEROLATERAL STEMI' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 15:52:58
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:04:30
User entered 'antiplatelet therapy for inferolateral STEMI'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:34
User entered '325'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:35
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:38
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:39
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:43
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:44
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:46
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:48
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:52
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:54
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:36:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:36:23
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:36:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:35:54
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:56
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:04:58
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:35:54
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User entered empty.	System	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User entered empty.	System	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:09
User entered empty.	System	09 Nov 2020 21:35:54

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 15:57:43
Data point term sent to Coder	System	16 Nov 2020 15:56:43
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 15:56:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:05:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:37:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:37:38
Data point term sent to Coder	System	09 Nov 2020 21:37:16
User entered 'brilinta'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:05:54
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:29:45
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:03
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:56:32
User entered 'INFEROLATERAL STEMI' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 15:56:13
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:05:50
User entered 'antiplatelet therapy for inferolateral STEMI'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:05:58
User entered '180'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:02
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:04
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:05
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:09
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:10
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:12
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:14
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:15
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:17
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:18
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:06:19
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User entered empty.	System	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User entered empty.	System	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:13
User entered empty.	System	09 Nov 2020 21:37:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ADENOSINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:09:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 09:09:56
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4)	16 Nov 2020 15:58:49 16 Nov 2020 15:58:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: ADENOSINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:43:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:43:40
Data point term sent to Coder User entered 'adenosine'	System Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:38:17 09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:07:56
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:37:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 21:37:57
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 21:37:57
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:37:50
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:11
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:58:13
User entered 'DURING PCI for inferolateral STEMI' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 15:58:07
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:08:53
User entered 'during PCI'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication and it appear to exceed the maximum recommended daily dose for this medication. Please review and update the dose or frequency if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 17:11:46
Query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication and it appear to exceed the maximum recommended daily dose for this medication. Please review and update the dose or frequency if appropriate. Otherwise, clarify.' answered with 'this is reported in the medical records from SAE incident. no action necessary' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	30 Jan 2021 18:54:18
User opened query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication and it appear to exceed the maximum recommended daily dose for this medication. Please review and update the dose or frequency if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:48:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:02
User entered '1'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:08
User entered 'g (g)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:11
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:13
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:14
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:16
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:17
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:20
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:22
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:23
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:25
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:26
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User entered empty.	System	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User entered empty.	System	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:18
User entered empty.	System	09 Nov 2020 21:37:50

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, PRODUCT: CONTRAST MEDIA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Dec 2020 18:19:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Dec 2020 18:19:24
Data point term sent to Coder	System	25 Dec 2020 18:02:36
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' canceled (Site from System).	Coder Import (b) (4)	25 Dec 2020 18:02:29
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4)	24 Nov 2020 12:26:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:10
Data point term sent to Coder	System	09 Nov 2020 21:39:19
User entered 'intravenous contrast'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:12
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:13
User entered 'during PCI'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:16
User entered '190'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:17
User entered 'mL (mL)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:20
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:21
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:23
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:26
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:27
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:29
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:30
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:32
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:10:33
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:38:36
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User entered empty.	System	09 Nov 2020 21:38:36

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User entered empty.	System	09 Nov 2020 21:38:36

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:21
User entered empty.	System	09 Nov 2020 21:38:36

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
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: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:45:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:45:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:25:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:25:35
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4) (b) (4)	16 Nov 2020 15:59:50 16 Nov 2020 15:59:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:07
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: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:32:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:32:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Nov 2020 21:40:20
User entered 'INTRAVENOUS normal saline solution (bolus)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:11
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:24
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:59:54
User entered 'DURING PCI for inferolateral STEMI' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 15:59:48
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:13:17
User entered 'during PCI'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:43:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:03:14
Query 'Per CDM: Site response is noted. Please add data for dose per administration.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:04:14
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 22:58:22
User entered 'unk' reason for change: Data Entry Error	Sandra Francisco (b) (4)	23 Nov 2020 22:58:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:30:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:55:41
User opened query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:55:37
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:39:40
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:39:28
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:03:21
Query 'Per CDM: Site response is noted. Please add data for dose unit.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:04:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:30:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:55:52
User opened query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:55:51
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:39:42
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:39:28
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:30:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:19
User entered 'once (ONCE)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:20
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:12:21
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:00
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:05
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:06
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:08
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:09
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:10
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:39:28
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User entered empty.	System	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User entered empty.	System	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:25
User entered empty.	System	09 Nov 2020 21:39:28

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:04:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:04:22
Data point term sent to Coder	System	23 Nov 2020 23:03:38
Coding entries removed.	Sandra Francisco (b) (4)	23 Nov 2020 23:03:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:53
Data point term sent to Coder	System	16 Nov 2020 16:00:52
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 16:00:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 05:45:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 05:45:48
Data point term sent to Coder	System	09 Nov 2020 21:48:32
Data point term sent to Coder	System	09 Nov 2020 21:47:28
User entered 'morphine sulfate'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:13:39
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:15:31
User entered 'INFEROLATERAL STEMI' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:03:02
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4)	
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:31
User entered 'CHEST PAIN related to inferolateral STEMI' reason for change: New Information	Shetel Anassi (b) (4)	16 Nov 2020 16:00:34
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Shetel Anassi (b) (4)	16 Nov 2020 16:00:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'chest pain' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 21:13:47
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.	System	09 Nov 2020 21:47:34
	System	09 Nov 2020 21:47:34
	Sandra Francisco (b) (4)	09 Nov 2020 21:47:34
	(b) (4)	
	System	09 Nov 2020 21:47:13
	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:15:33
User closed query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:00:09
Query 'Per CDM: Site response is noted. Please add data for dose per administration.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:03:24
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:03:02
User entered 'unk' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	23 Nov 2020 23:03:02
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:30:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:56:04
User opened query 'Per CDM: Site response is noted. Please add data for dose per administration.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:56:02
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:47:56
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:47:13
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:01:33
Query 'Per CDM: Site response is noted. Please add data for dose unit.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:03:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:30:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:56:15
User opened query 'Per CDM: Site response is noted. Please add data for dose unit.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:56:13
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:47:59
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:47:13
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:31:01
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for frequency.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:02:07
Query 'Per CDM: Site response is noted. Please add data for frequency.' answered with 'Medical records indicate medication was given but dosing and frequency was not documented ' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:03:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:31:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:56:26
User opened query 'Per CDM: Site response is noted. Please add data for frequency.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:56:24
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:48:02
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 21:47:13
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:31:06
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:16:57
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:47:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:17:00
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:17:03
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:17:04
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 16:15:43
User closed query 'Per CDM: Site response is noted. Please add data for ongoing.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 08:48:42
Query 'Per CDM: Site response is noted. Please add data for ongoing.' answered with 'updated: EDC reflects source' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:03:42
DataPoint Un-verified.	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:03:18
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:03:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:31:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:56:40
User opened query 'Per CDM: Site response is noted. Please add data for ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:56:38
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 21:48:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	09 Nov 2020 21:47:51
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:51
	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:08
User closed query 'Per source, stop date was 04Oct2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 21:40:04
Query 'Per source, stop date was 04Oct2020. Please update.' answered with 'updated: EDC reflects source' (Site from CRA).	Sandra Francisco (b) (4)	23 Nov 2020 23:03:53
User entered '04 Oct 2020' reason for change: Per Query Resolution	(b) (4)	23 Nov 2020 23:03:18
User opened query 'Per source, stop date was 04Oct2020. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:31:48
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:47:51
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Nov 2020 21:47:13
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:17:07
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User entered empty.	System	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User entered empty.	System	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:29
User entered empty.	System	09 Nov 2020 21:47:13

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 17:16:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 17:16:51
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 17:15:40 08 Apr 2021 17:15:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:00:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:00:37
Data point term sent to Coder User entered 'Aspirin'	System Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:59:51 09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:05
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:15:03
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
DataPoint Un-verified.	Carrie Kibler (b) (4)	08 Apr 2021 17:15:22
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 17:15:22
User entered 'Coronary artery disease' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 17:15:22
User signature succeeded.	(b) (4) Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:40
User entered 'CAD'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:42
User entered '81'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:45
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:19:47
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:32:47
User closed query 'Per source, this is taken once daily.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:31:41
Query 'Per source, this is taken once daily.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 16:01:07
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 16:00:59
User opened query 'Per source, this is taken once daily.' (Site from CRA).	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Nov 2020 21:22:05
	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:09
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:11
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:13
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:14
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:16
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:17
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:06:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:06:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	10 Nov 2020 18:06:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 21:58:55
User entered empty.	System	09 Nov 2020 21:58:55
	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:22:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:06:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:06:02
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	10 Nov 2020 18:06:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Nov 2020 21:58:55
	Sandra Francisco (b) (4)	09 Nov 2020 21:58:55
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User entered '1'	System	16 Nov 2020 16:00:59
User entered '2'	System	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User entered '1'	System	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:18:32
User entered '804 (804)'	System	09 Nov 2020 21:58:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:46:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:46:12
Data point term sent to Coder	System	23 Nov 2020 23:11:44
Data point term sent to Coder	System	23 Nov 2020 23:08:42
Coding entries removed.	Sandra Francisco (b) (4)	23 Nov 2020 23:08:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 11:07:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 11:07:14
Data point term sent to Coder	System	16 Nov 2020 16:03:57
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 16:03:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:25:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 22:17:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 22:17:36
Data point term sent to Coder	System	09 Nov 2020 22:01:55

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User		Time (GMT)
User entered 'DOCUSATE SODIUM' reason for change: New Information	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:01:20
User entered 'DOCUSATE' reason for change: Data Entry Error	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:00:57
Data point term sent to Coder	System		09 Nov 2020 22:00:54
User entered 'docosate'	Sandra Francisco (b) (4)	(b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:32:06
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'prophylaxis for CONSTIPATION DURING HOSPITALIZATION FOR INFEROLATERAL STEMI' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:11:16
User entered 'CONSTIPATION during hospitalization for inferolateral STEMI' reason for change: Data Entry Error	Sandra Francisco (b) (4)	23 Nov 2020 23:08:31
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:44:25
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 16:03:29
User entered 'CONSTIPATION of inferolateral STEMI' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 16:03:22
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:25:52
User entered 'constipation'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:01
User entered '100'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:09
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:14
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Carrie Kibler (b) (4)	17 Dec 2020 17:39:02
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Carrie Kibler (b) (4)	17 Dec 2020 17:39:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:26:38
User entered 'other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:13:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:16:53
Query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify.	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:39:17
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:39:02
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:39:02
User opened query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:54:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:40
User entered 'every 12 hours'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:42
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:46
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:50
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:51
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:08:31
User closed query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:26:59
Query 'Per CDM: Site response is noted. Please add data for Ongoing.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	17 Nov 2020 21:59:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 21:59:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:58:13
User opened query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:58:11
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 22:01:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:00:34
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:14:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '07 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:08:31
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:26:53
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:00:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 22:00:39
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 22:00:39
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:00:34
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User entered '2'	System	17 Dec 2020 17:39:02
User entered empty.	System	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User entered '1'	System	17 Dec 2020 17:39:02
User entered empty.	System	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:22
User entered '804 (804)'	System	17 Dec 2020 17:39:02
User entered empty.	System	09 Nov 2020 22:00:34

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:16:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:16:27
Data point term sent to Coder	System	23 Nov 2020 23:11:43
Coding entries removed.	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 06:31:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 06:31:52
Data point term sent to Coder	System	16 Nov 2020 16:09:05
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 16:08:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:23:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 22:03:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 22:03:38
Data point term sent to Coder	System	09 Nov 2020 22:02:56
User entered 'enoxaparin'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:32:29
User entered 'Yes (Y)' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:02:46
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'prophylaxis for DEEP VEIN THROMBOSIS' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:44:44
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 16:08:41
User entered 'DEEP VEIN THROMBOSIS due to inferolateral STEMI' reason for change: New Information	Shetel Anassi (b) (4)	16 Nov 2020 16:08:34
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 22:23:41
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:02:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 22:02:46
User entered 'deep vein thrombosis' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:02:46
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:02:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:40
User entered '40'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:47
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:52
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:51
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:54
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:56
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:02:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:58
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:24:59
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:25:02
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:32:39
User closed query 'Per CDM: Site response is noted. Please add data for Ongoing and "Was this medication taken for solicited event".' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:27:13
Query 'Per CDM: Site response is noted. Please add data for Ongoing and "Was this medication taken for solicited event".' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	17 Nov 2020 22:01:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 22:00:56
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:57:40
User opened query 'Per CDM: Site response is noted. Please add data for Ongoing and "Was this medication taken for solicited event".' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:57:39
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 22:02:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:02:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
User entered '07 Oct 2020' reason for change: New Information	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:10:44
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:32:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:47
User closed query 'Per source, this is No. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 21:40:45
Query 'Per source, this is No. Please update.' answered with 'updated: EDC reflects source' (Site from CRA).	Sandra Francisco (b) (4)	23 Nov 2020 23:09:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 23:08:59
User opened query 'Per source, this is No. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:33:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 22:00:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:57:42
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 22:02:53
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:02:19
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:02:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User entered '1'	System	09 Nov 2020 22:02:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User entered '1'	System	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:41
User entered '804 (804)'	System	09 Nov 2020 22:02:19

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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)	24 Nov 2020 04:23:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 04:23:08
Data point term sent to Coder	System	23 Nov 2020 23:14:46
Coding entries removed.	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
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)	23 Nov 2020 08:01:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 08:01:18
Data point term sent to Coder	System	16 Nov 2020 16:07:00
Coding entries removed.	Shetel Anassi (b) (4)	16 Nov 2020 16:06:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:25:52
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)	10 Nov 2020 05:55:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[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. Data point term sent to Coder User entered 'sodium chloride 0.9%'	Coder Import (b) (4) (b) (4) System Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 05:55:26 09 Nov 2020 22:12:12 09 Nov 2020 22:11:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:25:55
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'hydration during hospitalization for inferolateral STEMI' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:44:49
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' answered with 'updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 16:08:09
User entered 'HYDRATION due to inferolateral STEMI' reason for change: Data Entry Error	Shetel Anassi (b) (4)	16 Nov 2020 16:06:39
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 22:26:20
User entered 'hydration'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Please consider updating the Dose per administration as it should be in Numeric.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 14:59:34
Query 'Per CDM: Please consider updating the Dose per administration as it should be in Numeric.' answered with 'updated per medical records. EDC reflects source' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 23:14:03
DataPoint Un-verified.	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
User entered '75' reason for change: Per Query Resolution	(b) (4)	
	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
User opened query 'Per CDM: Please consider updating the Dose per administration as it should be in Numeric.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 10:34:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:34
User entered '75mL/hour'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Per Query Resolution	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:26:37
User entered 'mL (mL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:16:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
User entered 'mL/hour' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:13:48
	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:26:39
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:42
User entered 'other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:17:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 22:12:20
User entered 'continuous IV hydration' reason for change: New Information	Sandra Francisco (b) (4)	09 Nov 2020 22:12:20
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Nov 2020 22:11:27
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:50
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:51
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:53
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:26:55
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:17:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:17:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Nov 2020 23:02:11
User entered '07 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Nov 2020 23:02:11
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	09 Nov 2020 22:11:27
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:11:27
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:17:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User entered empty.	System	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User entered empty.	System	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:46
User entered empty.	System	09 Nov 2020 22:11:27

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:25:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:37
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:55:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:55:26
Data point term sent to Coder	System	09 Nov 2020 22:14:14
User entered 'sodium chloride - Saline flush0.9%'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:42
User entered 'for IV flush'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:44
User entered '10'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:46
User entered 'mL (mL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:48
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:56
User entered 'other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:27:59
User entered 'every 12 hours'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:08
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:10
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:16
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:28:18
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:58:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:25:33
User closed query 'per source, conmeds pg.3, end date is noted as 04Oct2020, EDC is 07oct2020, please review and make corrections. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 21:25:12
Query 'per source, conmeds pg.3, end date is noted as 04Oct2020, EDC is 07oct2020, please review and make corrections. ' answered with 'data updated ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:16:08
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:16:01
User entered '04 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:16:01
User opened query 'per source, conmeds pg.3, end date is noted as 04Oct2020, EDC is 07oct2020, please review and make corrections. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:21:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Nov 2020 23:02:52
User entered '07 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	10 Nov 2020 23:02:52
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	09 Nov 2020 22:13:37
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:13:37
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:21:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User entered empty.	System	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User entered empty.	System	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:49
User entered empty.	System	09 Nov 2020 22:13:37

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:32:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: NICOTINIC ACID AND DERIVATIVES, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:48:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:48:26
Data point term sent to Coder	System	09 Nov 2020 22:24:29
User entered 'niacin extended release'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:32:58
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:22:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:49:22
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' answered with 'updated' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:55:36
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 22:32:53
User entered 'hyperlipidemia'	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:00
User entered '1000'	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:01
User entered 'mg (mg)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:03
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:05
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:06
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:08
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:21
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:33:25
User entered '04 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:27:36
Query 'Per CDM: Site response is noted. Please add data for Ongoing.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	17 Nov 2020 21:57:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 21:57:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:59:11
User opened query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:59:09
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 22:23:58
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:23:52
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 22:23:52

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNOSIDE [SENNOSIDE A+B] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:16:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 12:16:00
Data point term sent to Coder	System	23 Nov 2020 23:18:50
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	23 Nov 2020 23:18:01
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'ingredient name updated' (Site from System).	Sandra Francisco (b) (4)	23 Nov 2020 23:18:01
Data point term sent to Coder	System	23 Nov 2020 23:17:49
DataPoint Un-verified.	Sandra Francisco (b) (4)	23 Nov 2020 23:17:48
User entered 'SENNoside' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	23 Nov 2020 23:17:48
Data point term sent to Coder	System	23 Nov 2020 23:16:48

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 09:27:08
Data point term sent to Coder	System	17 Nov 2020 22:00:13
Coding entries removed.	Shetel Anassi (b) (4)	17 Nov 2020 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:34:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNOSIDE [SENNOSIDE A+B] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Nov 2020 22:26:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	09 Nov 2020 22:26:37
Data point term sent to Coder	System	09 Nov 2020 22:25:32
User entered 'senna'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:00
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'PROPHYLAXIS FOR CONSTIPATION during hospitalization for INFEROLATERAL STEM' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:16:05
User closed query 'Please enter indication as "Prophylaxis for Constipation due to inferolateral STEMI" (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:26:30
Query 'Please enter indication as "Prophylaxis for Constipation due to inferolateral STEMI" answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	17 Nov 2020 22:00:20
User entered 'Prophylaxis for Constipation due to inferolateral STEM' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 22:00:08
User opened query 'Please enter indication as "Prophylaxis for Constipation due to inferolateral STEMI" (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:51:37
User closed query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:51:37
Query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' answered with 'not related to SAE' (Site from CRA).	Shetel Anassi (b) (4)	16 Nov 2020 15:53:48
User opened query 'Please update indication to match SAE of inferolateral STEMI to link the medication to the SAE. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 22:34:30
User entered 'constipation'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:33
User entered '8.6'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:35
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:36
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Carrie Kibler (b) (4)	17 Dec 2020 17:40:17
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Carrie Kibler (b) (4)	17 Dec 2020 17:40:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 22:35:38
User entered 'other (OTHER)'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:17:04
Query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify.	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:40:35
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:40:17
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	17 Dec 2020 17:40:17
User opened query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "twice daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:54:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:39
User entered 'every 12 hours'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:41
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:54
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:35:59
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:16:05
User closed query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:27:47
Query 'Per CDM: Site response is noted. Please add data for Ongoing.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	17 Nov 2020 22:00:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	17 Nov 2020 22:00:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:59:26
User opened query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:59:24
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 22:24:47
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 22:24:38
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '07 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:16:05
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User entered '2'	System	17 Dec 2020 17:40:17
User entered empty.	System	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User entered '1'	System	17 Dec 2020 17:40:17
User entered empty.	System	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:06
User entered '804 (804)'	System	17 Dec 2020 17:40:17
User entered empty.	System	09 Nov 2020 22:24:38

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:40:01
Query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'THE FREQUENCY REMAIN THE SAME AS PREVIOUSLY; UPDATED IN TEHSOURCE DOCUMENT AND EDC' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 22:46:47
User opened query 'Per DM CLR: Was the frequency of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 19:29:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:45:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:45:54
Data point term sent to Coder	System	22 Mar 2021 21:44:36

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EAB) (1725)

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US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 21:44:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:35:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 23:35:37
Data point term sent to Coder	System	09 Nov 2020 23:19:29
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:19:03
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:19:03
User entered 'vitamin D' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:19:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:43:42
Data point term sent to Coder	System	09 Nov 2020 22:27:36
User entered 'brilinta'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:07:06
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Updated in Source Document and EDC' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:44:42
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 21:44:26
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:49:49
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'VITAMIN D DEFICIENCY' reason for change: New Information	(b) (4), (b) (6)	22 Mar 2021 21:44:26
User entered 'Vit D deficiency' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:19:03
User entered 'cardiovascular event prevention'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '50000' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:19:03
User entered '90'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'IU (IU)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:19:03
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:45:24
User entered 'other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 22:45:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'every week (QS)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:19:03
User entered 'twice daily (BID)'	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:32:19
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:45:24
User entered 'Q 10 DAYS' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 22:45:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '07 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:19:03
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 22:45:24
User entered '1'	System	09 Nov 2020 23:19:03
User entered '2'	System	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 22:45:24
User entered '1'	System	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 22:45:24
User entered '803 (803)'	System	09 Nov 2020 23:19:03
User entered '804 (804)'	System	09 Nov 2020 22:26:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 23:22:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 23:22:45
Data point term sent to Coder	System	09 Nov 2020 23:21:34
Coding entries removed.	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
Coding entries removed.	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered 'influenza vaccine' reason for change: Data Entry Error	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 22:53:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 22:53:37
Data point term sent to Coder	System	09 Nov 2020 22:36:51
User entered 'carvedilol'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'influenza' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0.5' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered '6.25'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mL (mL)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once (ONCE)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered 'twice daily (BID)'	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
reason for change: Data Entry Error	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '04 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:21:17
User entered '17 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User entered empty.	System	09 Nov 2020 23:21:17
User entered '2'	System	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User entered empty.	System	09 Nov 2020 23:21:17
User entered '1'	System	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:10
User entered empty.	System	09 Nov 2020 23:21:17
User entered '804 (804)'	System	09 Nov 2020 22:35:59

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
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.	Coder Import (b) (4)	15 Mar 2021 16:04:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 16:04:57
Data point term sent to Coder	System	12 Mar 2021 16:30:44
Coding entries removed.	Sandra Francisco (b) (4)	12 Mar 2021 16:29:47
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.	Coder Import (b) (4)	25 Dec 2020 09:48:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Dec 2020 09:48:20
Data point term sent to Coder	System	24 Dec 2020 19:23:25
Coding entries removed.	Carrie Kibler (b) (4)	24 Dec 2020 19:23:06
User entered 'PANTOPRAZOLE' reason for change: Data Entry Error	Carrie Kibler (b) (4)	24 Dec 2020 19:23:06
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.	Coder Import (b) (4)	10 Nov 2020 05:50:26

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[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. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Sandra Francisco (b) (4) (b) (4) Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 05:50:26 09 Nov 2020 23:23:35 09 Nov 2020 23:23:04 09 Nov 2020 23:23:04 09 Nov 2020 23:23:04
User entered 'pantoprazone' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 23:23:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 22:37:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'TOPROL'	Coder Import (b) (4) (b) (4) System Sandra Francisco (b) (4) (b) (4)	09 Nov 2020 22:37:40 09 Nov 2020 22:36:52 09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:31:30
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'updated EDC to answer query ' (Site from DM).	Sandra Francisco (b) (4)	12 Mar 2021 16:30:03
User entered 'prophylaxis for GERD' reason for change: Data Entry Error	Sandra Francisco (b) (4)	12 Mar 2021 16:29:47
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 21:31:36
User entered 'GERD' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered 'hypertension'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '40' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered '100'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered 'twice daily (BID)'	(b) (4)	
	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Intravenous (INTRAVENOUS)'	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
reason for change: Data Entry Error	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '04 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered '17 Oct 2020'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:27:58
Query 'Per CDM: Site response is noted. Please add data for Ongoing.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	17 Nov 2020 22:01:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 22:01:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 19:59:41
User opened query 'Per CDM: Site response is noted. Please add data for Ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 19:59:39
Query 'Data is required. Please complete.' answered with 'Will add data once available' (Site from System).	Sandra Francisco (b) (4)	09 Nov 2020 23:23:08
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 23:23:04
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	09 Nov 2020 23:23:04
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Sandra Francisco (b) (4)	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 23:23:04
User entered '2'	System	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 22:36:29

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med CARDIZEM was added/changed on 22 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 12:56:03
Query 'Per DM CLR: Con Med CARDIZEM was added/changed on 22 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Change in medication was performed by the cardiologist to address recovered Inferolateral STEMI (see AE#01) on 04 OCT 2020. Cardiazem 240 mg QD manages better both conditions, Hypertension and Status Post Inferolateral STEMI. New medication added by the cardiologist for new diagnostic (see AE #01)' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 21:46:19
User opened query 'Per DM CLR: Con Med CARDIZEM was added/changed on 22 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 21:31:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Dec 2020 09:41:20

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[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. Data point term sent to Coder User entered 'cardizem'	Coder Import (b) (4) (b) (4) System Carrie Kibler (b) (4) (b) (4)	25 Dec 2020 09:41:20 24 Dec 2020 19:24:26 24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'coronary artery disease'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '240'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '22 Oct 2020'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44
	(b) (4)	

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	Carrie Kibler (b) (4)	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Dec 2020 19:23:44

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 20:22:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 20:22:50
Data point term sent to Coder	System	12 Feb 2021 20:22:12
User entered 'Synthroid'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Hypothyroidism'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '150'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mcg'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 20:21:40

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses" ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:41:08
Query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"	(b) (4), (b) (6)	29 Mar 2021 15:45:47
' answered with 'The participant received the 1st dose - 17 Aug 2020 and dose 2 14 Sep 2020, more than 6 months after the Hydrocortisone treatment started. Highest dose considered for low cortisol level is greater than 15 mg PO daily ' (Site from DM).		
User opened query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses" ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:15:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:36:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:36:54
Data point term sent to Coder	System	12 Mar 2021 22:26:09
User entered 'HYDROCORTISONE'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:59:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'UPDATED IN EDC' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:30:34
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 10:20:26
User entered 'LOW CORTISOL LEVEL'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '10'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '04 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 22:25:15

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 07:24:41
Query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'NOT WORSENING. CHANGE IN DIABETES MEDICATION.' (Site from DM).	Carrie Kibler (b) (4)	08 Apr 2021 17:25:05
User opened query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:18:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:20:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:20:34
Data point term sent to Coder	System	24 Mar 2021 13:20:01
User entered 'TRULICITY'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'TYPE 2 DIABETES MELLITUS'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0.75'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'every week (QS)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '14 Dec 2020'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	24 Mar 2021 13:19:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 13:23:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 13:23:34
Data point term sent to Coder	System	24 Mar 2021 13:23:03
User entered 'tdAP'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'PREVENTION OF TETANUS AND DIFTERIA'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0.5'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mL (mL)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once (ONCE)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '09 Nov 2020'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '09 Nov 2020'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User entered empty.	System	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User entered empty.	System	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:15
User entered empty.	System	24 Mar 2021 13:22:17

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: MEASLES VACCINES, PRODUCT: MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3), PRODUCTSYNONYM: MMR II - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:25:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 13:25:34
Data point term sent to Coder	System	24 Mar 2021 13:25:04
User entered 'MMR II'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'PREVENTION OF MUMPS, MEASLES, RUBELLA'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0.5'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'mL (mL)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'once (ONCE)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Aug 2020'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered '12 Aug 2020'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User entered empty.	System	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User entered empty.	System	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 11 Jun 2021 15:03:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:20:21
User entered empty.	System	24 Mar 2021 13:24:11

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 15:03:34

[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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:44:53
User closed query 'Per source, multiple procedures are reported. Please enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:44:52
Query 'Per source, multiple procedures are reported. Please enter in EDC.' answered with 'updated: EDC reflects source' (Site from CRA).	Sandra Francisco (b) (4)	23 Nov 2020 23:20:03
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	23 Nov 2020 23:19:49
User opened query 'Per source, multiple procedures are reported. Please enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 19:27:26
User entered 'No (N)'	Carrie Kibler (b) (4)	17 Aug 2020 22:44:51

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:16
User entered '04 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	23 Nov 2020 23:41:42

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:16
User entered 'percutaneous coronary intervention (PCI)'	Sandra Francisco (b) (4) (b) (4)	23 Nov 2020 23:41:42

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:16
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	23 Nov 2020 23:42:57
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	23 Nov 2020 23:42:41
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4) (b) (4)	23 Nov 2020 23:41:42

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:03:34

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:16
User entered empty; reason for change Per Query Resolution	Sandra Francisco (b) (4)	23 Nov 2020 23:42:57
User entered 'AE #01 - inferolateral STEMI' reason for change: New Information	Sandra Francisco (b) (4)	23 Nov 2020 23:42:41
User entered empty.	Sandra Francisco (b) (4)	23 Nov 2020 23:41:42

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:24
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 16:46:58
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:24
User entered 'intravascular ultrasound (IV US)'	Sandra Francisco (b) (4)	24 Nov 2020 16:46:58

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:24
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:46:58

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:24
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 16:46:58
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:34
User entered '04 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:47:17

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:34
User entered 'left heart catheterization'	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:47:17

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:34
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:47:17
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:34
User entered empty.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:47:17

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:36
User entered '04 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:48:20

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:36
User entered 'selective coronary angiogram'	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:48:20

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:36
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:20

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:36
User entered empty.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:48:20

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:40
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:38
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Un-verified.	Sandra Francisco (b) (4)	24 Nov 2020 18:12:13
User entered 'ULTRASOUND GUIDED ACCESS THROUGH right FEMORAL ARTERY' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	24 Nov 2020 18:12:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:40
User entered 'ultrasound guided access through left femoral artery'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:38
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:40
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:38
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:40
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 16:48:38
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:44
User entered '05 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:58
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:44
User entered 'transthoracic echocardiogram with doppler'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:58

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:44
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:48:58

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:44
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 16:48:58

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:48
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:48
User entered 'chest x ray'	Sandra Francisco (b) (4)	24 Nov 2020 16:49:14

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:48
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:48
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 16:49:14
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:22:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:52
User entered '04 Oct 2020'	Sandra Francisco (b) (4)	24 Nov 2020 16:49:25
	(b) (4)	

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:03:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:22:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
User closed query 'Per DM CLR: Note that there is another entry #10 (EKG) with the same date. Please review if this is a duplicate, and if so either correct dates or remove duplicate data. Update eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 09:17:38
Query 'Per DM CLR: Note that there is another entry #10 (EKG) with the same date. Please review if this is a duplicate, and if so either correct dates or remove duplicate data. Update eCRF as appropriate. Otherwise, provide clarification. ' answered with 'EKG PERFORMED BEFORE AND AFTER PERCUTANEOUS CORONARY INTERVENTION - THE SAME PROCEDURE - UPDATED IN SOURCE DCUMENT AND EDC' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 22:04:53
User opened query 'Per DM CLR: Note that there is another entry #10 (EKG) with the same date. Please review if this is a duplicate, and if so either correct dates or remove duplicate data. Update eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:01:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:52
User entered 'EKG'	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 16:49:25

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:03:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:22:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:52
User entered 'Adverse Event (AE)'	Sandra Francisco (b) (4)	24 Nov 2020 16:49:25

US3862021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:03:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:22:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:45:52
User entered empty.	Sandra Francisco (b) (4)	24 Nov 2020 16:49:25
	(b) (4)	

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'USA-US121-2020-MRNA-1273-P301000002'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:58
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:11
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Hana' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Hana'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'El Sahly' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'El Sahly'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Baylor College of Medicine One Baylor Plaza' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'One Baylor Plaza, MS 280'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Houston' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Houston'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'TX' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'TX'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '77030' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '77030'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'US'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 21:47:30
User entered '3'	System	12 Oct 2020 15:46:10
User entered '2'	System	07 Oct 2020 14:05:26
User entered '1'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'USA-US121-2020-MRNA-1273-P301000002'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:58
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:11
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Hana' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Hana'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'El Sahly' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'El Sahly'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Baylor College of Medicine One Baylor Plaza' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'One Baylor Plaza, MS 280'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Houston' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Houston'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'TX' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'TX'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '77030' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '77030'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'US'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 21:47:30
User entered '3'	System	12 Oct 2020 15:46:10
User entered '2'	System	07 Oct 2020 14:05:26
User entered '1'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:03:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
User entered '06/Oct/2020 14:38'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:03:34

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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'USA-US121-2020-MRNA-1273-P301000002'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:58
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:11
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Hana' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Hana'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'El Sahly' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'El Sahly'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Baylor College of Medicine One Baylor Plaza' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'One Baylor Plaza, MS 280'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Houston' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Houston'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'TX' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'TX'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '77030' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '77030'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'US'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 21:47:30
User entered '3'	System	12 Oct 2020 15:46:10
User entered '2'	System	07 Oct 2020 14:05:26
User entered '1'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:03:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
User entered '07/Oct/2020 10:05'	System	07 Oct 2020 14:05:26

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:03:34

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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 14:05:26

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'USA-US121-2020-MRNA-1273-P301000002'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:58
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:11
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Hana' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Hana'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'El Sahly' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'El Sahly'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Baylor College of Medicine One Baylor Plaza' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'One Baylor Plaza, MS 280'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Houston' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Houston'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'TX' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'TX'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '77030' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '77030'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'US'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 21:47:30
User entered '3'	System	12 Oct 2020 15:46:10
User entered '2'	System	07 Oct 2020 14:05:26
User entered '1'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:03:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
User entered '12/Oct/2020 15:46'	System	12 Oct 2020 15:46:10

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:03:34

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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 15:46:10

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'USA-US121-2020-MRNA-1273-P301000002'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:28:58
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'Yes (Y)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:11
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:38:45
User entered 'No (N)'	System	06 Oct 2020 14:38:21

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Hana' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Hana'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'El Sahly' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'El Sahly'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Baylor College of Medicine One Baylor Plaza' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'One Baylor Plaza, MS 280'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'Houston' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'Houston'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered 'TX' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'TX'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:47:15
Un-reviewed for Safety.	System	12 Oct 2020 15:46:10
User entered empty.	System	12 Oct 2020 15:46:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:45:57
User entered '77030' reason for change: New Information	Coni Cheesman (b) (4)	10 Oct 2020 21:12:46
Un-reviewed for Safety.	System	07 Oct 2020 14:05:26
User entered empty.	System	07 Oct 2020 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered '77030'	Coni Cheesman (b) (4)	06 Oct 2020 21:15:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 21:29:29
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:05:17
User entered 'US'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Jun 2021 15:03:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 21:47:30
User entered '3'	System	12 Oct 2020 15:46:10
User entered '2'	System	07 Oct 2020 14:05:26
User entered '1'	System	06 Oct 2020 14:38:52

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:03:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
User entered '02/Nov/2020 21:47'	System	02 Nov 2020 21:47:30

US3862021

Folder: SAE USA-US121-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:03:34

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 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:11:49
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 21:47:30