

US3352213 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:11:19

All time stamps listed in this document are displayed in GMT

US3352213

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Participant ID

US3352213

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

US3352213

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:44

Generated On: 09 Jun 2021 17:11:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3352213

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3352213

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3352213

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3352213

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 13:17:43

Generated On: 09 Jun 2021 17:11:19

Were any significant conditions reported?

Yes ☒

No ☐

US3352213

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	CORONARY ARTERY DISEASE (HIGH RISK)
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3352213

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	VARICOSE VEINS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	CORONARY ARTERY BYPASS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
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

US3352213

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3352213

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 13:17:42

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:17:47

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:57
Height (<i>xxx.x</i>)	175.0 cm
Weight (<i>xxx.x</i>)	99.3 kg
BMI (<i>xxx.x</i>)	32.42449 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352213

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:43

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3352213

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 13:17:43

Generated On: 09 Jun 2021 17:11:19

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

CONSTRUCTION WORKER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3352213

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 13:17:43

Generated On: 09 Jun 2021 17:11:19

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	

US3352213

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	22 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
------------	--------

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 144752

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 ☒

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Height	ND - Not Done
Weight	ND - Not Done

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:57
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	15:49 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 15:49
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:17:47

Generated On: 09 Jun 2021 17:11:19

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 15:19 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 15:19

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

US3352213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:47

Generated On: 09 Jun 2021 17:11:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 AUG 2020

Collection time (00:00-23:59)

14:49 (24 HR)

Collection date and time (derived)

22 AUG 2020 14:49

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 13:17:47

Generated On: 09 Jun 2021 17:11:19

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:28	22 AUG 2020 14:28
Nasopharyngeal Swab 2	No		

US3352213

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:47

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 15:56

PC Open Date & Time

22 AUG 2020 15:39

PC Close Date & Time

22 AUG 2020 18:09

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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 99.0 °F

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

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

PC Time Stamp	22 AUG 2020 20:11
PC Open Date & Time	22 AUG 2020 19:04
PC Close Date & Time	23 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

98.8 °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

23 AUG 2020 19:21

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:31

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

98.5 °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

25 AUG 2020 20:46

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 19:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

27 AUG 2020 20:50

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

99.5 °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

28 AUG 2020 20:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

22 AUG 2020 15:56

PC Open Date & Time

22 AUG 2020 15:39

PC Close Date & Time

22 AUG 2020 18:09

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

22 AUG 2020 20:12

PC Open Date & Time

22 AUG 2020 19:04

PC Close Date & Time

23 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 19:22

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

24 AUG 2020 19:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

25 AUG 2020 20:46

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

26 AUG 2020 19:44

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

27 AUG 2020 20:51

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

28 AUG 2020 20:18

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 15:57
PC Open Date & Time	22 AUG 2020 15:39
PC Close Date & Time	22 AUG 2020 18:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 20:12
PC Open Date & Time	22 AUG 2020 19:04
PC Close Date & Time	23 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

51 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:23
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

53 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:34
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

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 ☒

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:48
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

57 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 19:45
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

59 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:53
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

61 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:19
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3352213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	19 SEP 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
------------	--------

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 12:00
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 SEP 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 13:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 19 SEP 2020 12:42

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

US3352213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 SEP 2020

Collection time (00:00-23:59)

12:09 (24 HR)

Collection date and time (derived)

19 SEP 2020 12:09

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Collection date (dd MMM yyyy)			19 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:02	19 SEP 2020 12:02
Nasopharyngeal Swab 2	No		

US3352213

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:48

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 SEP 2020 13:19

PC Open Date & Time

19 SEP 2020 13:02

PC Close Date & Time

19 SEP 2020 15:32

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	19 SEP 2020 19:52
PC Open Date & Time	19 SEP 2020 16:27
PC Close Date & Time	20 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

98.7 °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

20 SEP 2020 19:02

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

22 SEP 2020 20:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:09

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

97.5 °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

25 SEP 2020 19:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

19 SEP 2020 13:20

PC Open Date & Time

19 SEP 2020 13:02

PC Close Date & Time

19 SEP 2020 15:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

19 SEP 2020 19:53

PC Open Date & Time

19 SEP 2020 16:27

PC Close Date & Time

20 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 19:02

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 19:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:06

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:04

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 19:10

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 19:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 13:21
PC Open Date & Time	19 SEP 2020 13:02
PC Close Date & Time	19 SEP 2020 15:32

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 19:54
PC Open Date & Time	19 SEP 2020 16:27
PC Close Date & Time	20 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

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 ☒

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:03
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

99 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 19:34
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

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 ☒

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:07
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

103 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

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 ☒

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 19:10
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

107 of 2442

EAB) (1725)

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 19:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3352213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	17 OCT 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
------------	--------

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 OCT 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	17 OCT 2020 09:30
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 OCT 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

17 OCT 2020 09:40

US3352213

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 11:35:52

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

31 OCT 2020 19:46:45

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 12:52:00
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

19 NOV 2020 15:42:53

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:40:17
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

02 DEC 2020 20:19:26

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 12:03:37
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 DEC 2020 14:37:51
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

01 JAN 2021 12:20:12

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

05 JAN 2021 07:40:02

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

12 JAN 2021 08:37:43

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 14:57:19
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

25 JAN 2021 11:09:57

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 17:14:41
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

09 FEB 2021 09:37:45

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

16 FEB 2021 08:38:17

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 09:08:14

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 13:01:51
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

08 MAR 2021 12:00:54

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 19:25:16
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

23 MAR 2021 12:10:08

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

29 MAR 2021 21:10:21

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

05 APR 2021 19:13:42

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

12 APR 2021 14:47:14

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

20 APR 2021 10:30:15

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 21:25:30
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 09:56:27
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2021 00:01
Patient Cloud Close Date & Time	20 AUG 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	15 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 NOV 2021 23:59
---	-------------------

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	24 DEC 2021 23:59
---	-------------------

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	27 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	31 DEC 2021 23:59
---	-------------------

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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°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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	25 JUL 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 JUL 2022 23:59
---	-------------------

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2022 23:59
---	-------------------

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3352213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:11:19

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
Yes	Yes	28 FEB 2021 13:29:46

US3352213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	18 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 MAR 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 11:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352213

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

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

Collection date (dd MMM yyyy)	18 MAR 2021
-------------------------------	-------------

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

Collection date and time (derived)	18 MAR 2021 11:31
------------------------------------	-------------------

US3352213

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:49

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352213

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:11:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352213

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	16 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3352213

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	16 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3352213

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Height	
Weight	
BMI (xxx.x)	

US3352213

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 11:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 12:36
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 JAN 2021

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 12:06

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

US3352213

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

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

Collection date (dd MMM yyyy)	16 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:53 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 JAN 2021 11:53
------------------------------------	-------------------

US3352213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

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

Collection date (dd MMM yyyy)	16 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:42
---------------------------------	-------

Collection Date and Time (derived)	16 JAN 2021 11:42
------------------------------------	-------------------

US3352213

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

THREE ATTEMPTS MADE.
SUBJECT DID NOT ANSWER.

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	24 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
------------	-------

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:38
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 12:11
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3352213

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3352213

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 11:41 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 11:41

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

What was the frequency of the study treatment dosing? ONCE

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

US3352213

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352213

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:17:41

Generated On: 09 Jun 2021 17:11:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352213

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

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

Visit date (dd MMM yyyy)	18 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
------------	-------

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:15 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 11:15
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352213

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352213

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:17:39

Generated On: 09 Jun 2021 17:11:19

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

Collection date (<i>dd MMM yyyy</i>)	18 MAR 2021
--	-------------

Collection time (<i>00:00-23:59</i>)	11:31 (24 HR)
--	---------------

Collection date and time (derived)	18 MAR 2021 11:31
------------------------------------	-------------------

US3352213

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

AEID	USA-US066-2021-MRNA-1273-P30 1000006
Adverse event	CEREBROVASCULAR ACCIDENT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	348 of 2442

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

SUBJECT REPORTED THAT HE
HAD A STROKE ON JANUARY
29TH AND WAS DISCHARGED
03FEB2021. SUBJECT IS
CURRENTLY PRESENTING
SPEECH DIFFICULTIES AND
WEAKNESS TO HIS RIGHT SIDE.
CONSIDERING SERIOUS EVENT
UNCLEAR HISTORY PROVIDED
HE WILL NO BE ABLE TO
RECEIVE HIS SECOND DOSE
TODAY. CURRENTY DOING
THERAPY.

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

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

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 True

Concomitant Medication False

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 SUBJECT HAD A
CEREBROVASCULAR
ACCIDENT; ANEMIA WAS A
FINDING FROM THE
LABORATORIES THAT WERE
DONE. ACORDING TO MEDICAL
RECORDS NO TREATMENT WAS
PROVIDED.

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

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)	

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

AEID

Adverse event

WORSENING OF
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

354 of 2442

EAB) (1725)

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

AEID	
Adverse event	WOUND OF RIGHT FOOT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2442

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PENDING MEDICAL RECORDS FROM THE HOPITAL TO DOCUMENT TREATMENT GIVEN.
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)	0

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

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

Yes ☒

No ☐

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

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication METOPROLOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication NIFEDIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 60

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)

363 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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)

367 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 0.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication GENTAMICIN TOPICAL 0.01%

Prophylaxis Yes ☐
No ☒

Indication WOUND OF RIGHT FOOT

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication WOUND OF RIGHT FOOT

Dose per administration 2

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)

375 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION.

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication WOUND OF RIGHT FOOT

Dose per administration 2

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)

381 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 1 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		1 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication SANTYL

Prophylaxis Yes ☐
No ☒

Indication WOUND OF RIGHT FOOT

Dose per administration 1

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

If dose unit is Other, specify APPLICATION.

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication CEREBROVASCULAR ACCIDENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication ROSUVASTATIN (CRESTOR)

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 2 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

Name of Medication OXYBUTYNIN

Prophylaxis Yes ☐
No ☒

Indication URINARY FREQUENCY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 2442

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:16:21

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 13:16:22

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 JAN 2021	X RAY CHEST	Adverse Event	
29 JAN 2021	CT OF THE BRAIN WITHOUT CONTRAST.	Adverse Event	
29 JAN 2021	ECG	Adverse Event	
30 JAN 2021	MRI BRAIN WITHOUT CONTRAST	Adverse Event	
30 JAN 2021	X RAY ANKLE COMPLETE RIGHT	Adverse Event	
01 FEB 2021	CT SCAN OF THE BRAIN WITHOUT CONTRAST	Adverse Event	
13 FEB 2021	OCCUPATIONAL THERAPY	Adverse Event	
13 FEB 2021	SPEECH THERAPY	Adverse Event	

US3352213

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:11:19

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

US3352213

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:11:19

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 ☐

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:26
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

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/FEB/2021 11:46
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

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/MAR/2021 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/MAR/2021 12:50
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

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 13:17:40

Generated On: 09 Jun 2021 17:11:19

SAEID	USA-US066-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/APR/2021 11:49
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

US3352213 (Prod: Research Centers of America - ERG)

US3352213

Form: Participant Creation

Generated On: 09 Jun 2021 17:11:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'US3352213'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:54:12

US3352213

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:29:28

US3352213

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:54:13

US3352213

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Aug 2020 20:29:28

US3352213

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'SCRN'	System	22 Aug 2020 20:29:28

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:54:14

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '62'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'YEARS'	System	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '62'	System	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Male (M)'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'I'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:11:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:29:40

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Aug 2020'	System	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2020'	System	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 19:41:01

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:54:13

US3352213

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'I'	System	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:11:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:29:56

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:31:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:31:18
Data point term sent to Coder	System	22 Aug 2020 20:30:20
User entered 'PRESBYOPIA'	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2013'	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2013'	System	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2013'	System	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:30:15

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
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)	22 Aug 2020 20:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:32:18
Data point term sent to Coder	System	22 Aug 2020 20:31:21
User entered 'HYPERTENSION'	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 1995'	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 1995'	System	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '1995'	System	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:30:42

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 04:55:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 04:55:41
Data point term sent to Coder	System	22 Aug 2020 20:31:21
User entered 'CORONARY ARTERY DISEASE (HIGH RISK)'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2008'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2008'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2008'	System	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2008'	System	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2008'	System	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2008'	System	22 Aug 2020 20:31:16

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Vascular disorders, HLT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:33:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:33:19
Data point term sent to Coder	System	22 Aug 2020 20:32:22
User entered 'VARICOSE VEINS'	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2013'	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2013'	System	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2013'	System	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	22 Aug 2020 20:31:44

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:35:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 20:35:19
Data point term sent to Coder	System	22 Aug 2020 20:34:27
User entered 'CORONARY ARTERY BYPASS'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'un UNK 2008'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'un UNK 2008'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2008'	System	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2008'	System	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2008'	System	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2008'	System	22 Aug 2020 20:33:42

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
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)	19 Feb 2021 14:04:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:04:48
Data point term sent to Coder	System	19 Feb 2021 14:03:44
User entered 'HYPERLIPIDEMIA'	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2016'	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2016'	System	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2016'	System	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	19 Feb 2021 14:02:57

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:31:35
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Condition has ended as of 2016 subject is not taking medications ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:55:12
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:41:27
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 14:05:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 14:05:48
Data point term sent to Coder	System	19 Feb 2021 14:04:45
User entered 'ATRIAL FIBRILLATION'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'UN UNK 2016'	Surisaday Mederos (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	13 Apr 2021 15:44:16
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	13 Apr 2021 15:44:16
User entered 'UN UNK 2016'	Surisaday Mederos (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2016'	System	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2016'	System	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	13 Apr 2021 15:44:16
User entered 'Jan 2016'	System	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	13 Apr 2021 15:44:16
User entered '2016'	System	19 Feb 2021 14:04:23

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:06:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:06:49
Data point term sent to Coder	System	19 Feb 2021 14:05:46
User entered 'Osteoarthritis'	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'un UNK 2015'	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Jan 2015'	System	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2015'	System	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	19 Feb 2021 14:05:36

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
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)	23 Feb 2021 15:00:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 15:00:59
Data point term sent to Coder	System	23 Feb 2021 15:00:08
User entered 'Benign Prostatic Hyperplasia'	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'un Feb 2020'	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Feb 2020'	System	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2020'	System	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	23 Feb 2021 14:59:19

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:38:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:38:11
Data point term sent to Coder	System	13 Apr 2021 16:25:07
User entered 'urinary frequency'	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'un Feb 2020'	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'Feb 2020'	System	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '2020'	System	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered empty.	System	13 Apr 2021 16:24:18

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '13:57'	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered '22 Aug 2020 13:57'	System	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '175.0' cm	(b) (4), (b) (6)	22 Aug 2020 20:34:57
DataPoint set to visible.	System	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '99.3' kg	(b) (4), (b) (6)	22 Aug 2020 20:34:57
DataPoint set to visible.	System	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
Amendment Manager: User entered '32.42449'	System	17 Sep 2020 00:20:10
User entered '32.4'	System	22 Aug 2020 20:34:57
DataPoint set to visible.	System	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'kg/m2'	System	22 Aug 2020 20:34:57
DataPoint set to visible.	System	22 Aug 2020 19:41:07

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'bpm'	System	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'breaths/min'	System	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'mmHg'	System	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User entered 'mmHg'	System	22 Aug 2020 20:34:57

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05

US3352213

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05

US3352213

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:35:07

US3352213

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:35:07

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

[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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

[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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Construction Worker'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

[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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'I'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:35:53

US3352213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:36:04

US3352213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:36:04

US3352213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Aug 2020 20:36:04

US3352213

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'VISIT1'	System	22 Aug 2020 20:36:04

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:59:12

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '144752'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:59:12

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:59:12

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:36:23

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:36:23

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:36:23

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:36:23

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:36:23

US3352213

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:19

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:21:26
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	05 Nov 2020 19:26:24
User entered 'No (N)'	Matthew Muniz (b) (4)	05 Nov 2020 19:26:18
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:14:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:20:38

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '13:57'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered '22 Aug 2020 13:57'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.5' C	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Aug 2020 20:58:49
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	22 Aug 2020 20:58:49
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 20:58:49
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Aug 2020 20:38:13
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'bpm'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '13'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'breaths/min'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '145'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'mmHg'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '92'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'mmHg'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '15:49'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered '22 Aug 2020 15:49'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.5' C	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '71'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'bpm'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'breaths/min'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '137'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'mmHg'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '75'	(b) (4), (b) (6)	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'mmHg'	System	22 Aug 2020 20:38:13

US3352213

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:49:21

US3352213

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:49:21

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '15:19'	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered '22 Aug 2020 15:19'	System	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'ONCE'	System	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 19:41:41

US3352213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:49:45

US3352213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:49:45

US3352213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14:49'	(b) (4), (b) (6)	22 Aug 2020 20:49:45

US3352213

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered '22 Aug 2020 14:49'	System	22 Aug 2020 20:49:45

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14:28'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered '22 Aug 2020 14:28'	System	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered empty.	System	22 Aug 2020 20:49:56

US3352213

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:50:00

US3352213

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:17
User entered 'I'	System	22 Aug 2020 20:50:00

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:55:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6247233b-50d5-46ba-be64-99ba69de930d'	System	22 Aug 2020 19:56:05
User entered 'Yes (Y)'	System	22 Aug 2020 19:56:05

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:55:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6247233b-50d5-46ba-be64-99ba69de930d' User entered '98.7'	System	22 Aug 2020 19:56:05
	System	22 Aug 2020 19:56:05

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:55:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6247233b-50d5-46ba-be64-99ba69de930d'	System	22 Aug 2020 19:56:05
User entered 'No (N)'	System	22 Aug 2020 19:56:05

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6247233b-50d5-46ba-be64-99ba69de930d'	System	22 Aug 2020 19:56:05
User entered '22 Aug 2020 15:56'	System	22 Aug 2020 19:56:05

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 15:39'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 18:09'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:09:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '29aba5fc-9fc6-47fd-a3cc-d2fe9ce13afd'	System	23 Aug 2020 00:13:33
User entered 'Yes (Y)'	System	23 Aug 2020 00:13:33

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '29aba5fc-9fc6-47fd-a3cc-d2fe9ce13afd'	System	23 Aug 2020 00:13:33
User entered '99.0'	System	23 Aug 2020 00:13:33

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '29aba5fc-9fc6-47fd-a3cc-d2fe9ce13afd'	System	23 Aug 2020 00:13:33
User entered 'No (N)'	System	23 Aug 2020 00:13:33

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '29aba5fc-9fc6-47fd-a3cc-d2fe9ce13afd'	System	23 Aug 2020 00:13:33
User entered '22 Aug 2020 20:11'	System	23 Aug 2020 00:13:33

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 19:04'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 2'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0e36f8de-ca4e-4165-9d8b-686ff1bc73ce'	System	23 Aug 2020 23:21:49
User entered 'Yes (Y)'	System	23 Aug 2020 23:21:49

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:28', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0e36f8de-ca4e-4165-9d8b-686ff1bc73ce'	System	23 Aug 2020 23:21:49
User entered '98.8'	System	23 Aug 2020 23:21:49

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0e36f8de-ca4e-4165-9d8b-686ff1bc73ce'	System	23 Aug 2020 23:21:49
User entered 'No (N)'	System	23 Aug 2020 23:21:49

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:44', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0e36f8de-ca4e-4165-9d8b-686ff1bc73ce'	System	23 Aug 2020 23:21:49
User entered '23 Aug 2020 19:21'	System	23 Aug 2020 23:21:49

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 3'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:30:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1ab7dbf9-bcd6-42a1-a3bc-b942f3c584e6'	System	24 Aug 2020 23:31:42
User entered 'Yes (Y)'	System	24 Aug 2020 23:31:42

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:31:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1ab7dbf9-bcd6-42a1-a3bc-b942f3c584e6'	System	24 Aug 2020 23:31:42
User entered '98.5'	System	24 Aug 2020 23:31:42

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:31:13', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1ab7dbf9-bcd6-42a1-a3bc-b942f3c584e6'	System	24 Aug 2020 23:31:42
User entered 'No (N)'	System	24 Aug 2020 23:31:42

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:31:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1ab7dbf9-bcd6-42a1-a3bc-b942f3c584e6'	System	24 Aug 2020 23:31:42
User entered '24 Aug 2020 19:31'	System	24 Aug 2020 23:31:42

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 4'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:44:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ab48aac3-54d0-4a98-bc94-b4deb28c7946'	System	26 Aug 2020 00:46:04
User entered 'Yes (Y)'	System	26 Aug 2020 00:46:04

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:45:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ab48aac3-54d0-4a98-bc94-b4deb28c7946'	System	26 Aug 2020 00:46:04
User entered '98.5'	System	26 Aug 2020 00:46:04

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:45:48', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ab48aac3-54d0-4a98-bc94-b4deb28c7946'	System	26 Aug 2020 00:46:04
User entered 'No (N)'	System	26 Aug 2020 00:46:04

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ab48aac3-54d0-4a98-bc94-b4deb28c7946'	System	26 Aug 2020 00:46:04
User entered '25 Aug 2020 20:46'	System	26 Aug 2020 00:46:04

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 5'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:42:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '54831750-7da8-4914-a6e6-cdcdf9dcbcd5'	System	26 Aug 2020 23:43:47
User entered 'Yes (Y)'	System	26 Aug 2020 23:43:47

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:43:13', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '54831750-7da8-4914-a6e6-cdcdf9dcbcd5'	System	26 Aug 2020 23:43:47
User entered '97.5'	System	26 Aug 2020 23:43:47

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:43:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '54831750-7da8-4914-a6e6-cdcdf9dcbcd5'	System	26 Aug 2020 23:43:47
User entered 'No (N)'	System	26 Aug 2020 23:43:47

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:43:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '54831750-7da8-4914-a6e6-cdcdf9dcbcd5'	System	26 Aug 2020 23:43:47
User entered '26 Aug 2020 19:43'	System	26 Aug 2020 23:43:47

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 6'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:50:23', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a90a7f4f-72e8-4470-84b5-4c44399a2102'	System	28 Aug 2020 00:50:55
User entered 'Yes (Y)'	System	28 Aug 2020 00:50:55

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:50:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a90a7f4f-72e8-4470-84b5-4c44399a2102'	System	28 Aug 2020 00:50:55
User entered '98.5'	System	28 Aug 2020 00:50:55

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:50:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a90a7f4f-72e8-4470-84b5-4c44399a2102'	System	28 Aug 2020 00:50:55
User entered 'No (N)'	System	28 Aug 2020 00:50:55

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:50:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a90a7f4f-72e8-4470-84b5-4c44399a2102'	System	28 Aug 2020 00:50:55
User entered '27 Aug 2020 20:50'	System	28 Aug 2020 00:50:55

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 7'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:16:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '2be44e84-8a7b-4f6f-b923-a92ed958a5e8'	System	29 Aug 2020 00:17:59
User entered 'Yes (Y)'	System	29 Aug 2020 00:17:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:17:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '2be44e84-8a7b-4f6f-b923-a92ed958a5e8'	System	29 Aug 2020 00:17:59
User entered '99.5'	System	29 Aug 2020 00:17:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:17:52', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '2be44e84-8a7b-4f6f-b923-a92ed958a5e8'	System	29 Aug 2020 00:17:59
User entered 'No (N)'	System	29 Aug 2020 00:17:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:17:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '2be44e84-8a7b-4f6f-b923-a92ed958a5e8'	System	29 Aug 2020 00:17:59
User entered '28 Aug 2020 20:17'	System	29 Aug 2020 00:17:59

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:23', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75f286c1-3eff-45fa-89b1-d2830d614a6d'	System	22 Aug 2020 19:56:56
User entered 'None (1)'	System	22 Aug 2020 19:56:56

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75f286c1-3eff-45fa-89b1-d2830d614a6d'	System	22 Aug 2020 19:56:56
User entered 'No (N)'	System	22 Aug 2020 19:56:56

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:36', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75f286c1-3eff-45fa-89b1-d2830d614a6d'	System	22 Aug 2020 19:56:56
User entered 'No (N)'	System	22 Aug 2020 19:56:56

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75f286c1-3eff-45fa-89b1-d2830d614a6d'	System	22 Aug 2020 19:56:56
User entered 'None (1)'	System	22 Aug 2020 19:56:56

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:56:52', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75f286c1-3eff-45fa-89b1-d2830d614a6d'	System	22 Aug 2020 19:56:56
User entered '22 Aug 2020 15:56'	System	22 Aug 2020 19:56:56

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 15:39'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 18:09'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a98ef041-2e0e-4f1e-b992-554655684ca9'	System	23 Aug 2020 00:13:36
User entered 'None (1)'	System	23 Aug 2020 00:13:36

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:45', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a98ef041-2e0e-4f1e-b992-554655684ca9'	System	23 Aug 2020 00:13:36
User entered 'No (N)'	System	23 Aug 2020 00:13:36

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:11:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a98ef041-2e0e-4f1e-b992-554655684ca9'	System	23 Aug 2020 00:13:36
User entered 'No (N)'	System	23 Aug 2020 00:13:36

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a98ef041-2e0e-4f1e-b992-554655684ca9'	System	23 Aug 2020 00:13:36
User entered 'None (1)'	System	23 Aug 2020 00:13:36

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a98ef041-2e0e-4f1e-b992-554655684ca9'	System	23 Aug 2020 00:13:36
User entered '22 Aug 2020 20:12'	System	23 Aug 2020 00:13:36

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 19:04'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 2'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:50', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8cc7e883-47ef-4617-8495-291169b8d977'	System	23 Aug 2020 23:22:19
User entered 'None (1)'	System	23 Aug 2020 23:22:19

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:21:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8cc7e883-47ef-4617-8495-291169b8d977'	System	23 Aug 2020 23:22:19
User entered 'No (N)'	System	23 Aug 2020 23:22:19

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8cc7e883-47ef-4617-8495-291169b8d977'	System	23 Aug 2020 23:22:19
User entered 'No (N)'	System	23 Aug 2020 23:22:19

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:05', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8cc7e883-47ef-4617-8495-291169b8d977'	System	23 Aug 2020 23:22:19
User entered 'None (1)'	System	23 Aug 2020 23:22:19

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8cc7e883-47ef-4617-8495-291169b8d977'	System	23 Aug 2020 23:22:19
User entered '23 Aug 2020 19:22'	System	23 Aug 2020 23:22:19

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 3'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:32:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b8a93b9a-33f4-4095-bd35-1486c2979080'	System	24 Aug 2020 23:33:28
User entered 'None (1)'	System	24 Aug 2020 23:33:28

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:32:20', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b8a93b9a-33f4-4095-bd35-1486c2979080'	System	24 Aug 2020 23:33:28
User entered 'No (N)'	System	24 Aug 2020 23:33:28

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:32:43', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b8a93b9a-33f4-4095-bd35-1486c2979080'	System	24 Aug 2020 23:33:28
User entered 'No (N)'	System	24 Aug 2020 23:33:28

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:32:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b8a93b9a-33f4-4095-bd35-1486c2979080'	System	24 Aug 2020 23:33:28
User entered 'None (1)'	System	24 Aug 2020 23:33:28

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:33:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b8a93b9a-33f4-4095-bd35-1486c2979080'	System	24 Aug 2020 23:33:28
User entered '24 Aug 2020 19:33'	System	24 Aug 2020 23:33:28

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 4'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '96b293f2-818b-42d0-a8f7-3753bdf3c08a'	System	26 Aug 2020 00:46:55
User entered 'None (1)'	System	26 Aug 2020 00:46:55

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '96b293f2-818b-42d0-a8f7-3753bdf3c08a'	System	26 Aug 2020 00:46:55
User entered 'No (N)'	System	26 Aug 2020 00:46:55

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:38', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '96b293f2-818b-42d0-a8f7-3753bdf3c08a'	System	26 Aug 2020 00:46:55
User entered 'No (N)'	System	26 Aug 2020 00:46:55

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '96b293f2-818b-42d0-a8f7-3753bdf3c08a'	System	26 Aug 2020 00:46:55
User entered 'None (1)'	System	26 Aug 2020 00:46:55

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:46:53', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '96b293f2-818b-42d0-a8f7-3753bdf3c08a'	System	26 Aug 2020 00:46:55
User entered '25 Aug 2020 20:46'	System	26 Aug 2020 00:46:55

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 5'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:44:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c9fa99d-2981-4da3-8126-757d27322d53'	System	26 Aug 2020 23:44:54
User entered 'None (1)'	System	26 Aug 2020 23:44:54

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:44:29', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c9fa99d-2981-4da3-8126-757d27322d53'	System	26 Aug 2020 23:44:54
User entered 'No (N)'	System	26 Aug 2020 23:44:54

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:44:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c9fa99d-2981-4da3-8126-757d27322d53'	System	26 Aug 2020 23:44:54
User entered 'No (N)'	System	26 Aug 2020 23:44:54

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:44:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c9fa99d-2981-4da3-8126-757d27322d53'	System	26 Aug 2020 23:44:54
User entered 'None (1)'	System	26 Aug 2020 23:44:54

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:44:52', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c9fa99d-2981-4da3-8126-757d27322d53'	System	26 Aug 2020 23:44:54
User entered '26 Aug 2020 19:44'	System	26 Aug 2020 23:44:54

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 6'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:51:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '91015fa8-b008-44c4-9b74-3dd5d73d082a'	System	28 Aug 2020 00:51:53
User entered 'None (1)'	System	28 Aug 2020 00:51:53

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:51:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '91015fa8-b008-44c4-9b74-3dd5d73d082a'	System	28 Aug 2020 00:51:53
User entered 'No (N)'	System	28 Aug 2020 00:51:53

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:51:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '91015fa8-b008-44c4-9b74-3dd5d73d082a'	System	28 Aug 2020 00:51:53
User entered 'No (N)'	System	28 Aug 2020 00:51:53

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:51:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '91015fa8-b008-44c4-9b74-3dd5d73d082a'	System	28 Aug 2020 00:51:53
User entered 'None (1)'	System	28 Aug 2020 00:51:53

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:51:50', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '91015fa8-b008-44c4-9b74-3dd5d73d082a'	System	28 Aug 2020 00:51:53
User entered '27 Aug 2020 20:51'	System	28 Aug 2020 00:51:53

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 7'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '01a891c7-4d8a-46c7-a264-db18cf82471e'	System	29 Aug 2020 00:18:41
User entered 'None (1)'	System	29 Aug 2020 00:18:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '01a891c7-4d8a-46c7-a264-db18cf82471e'	System	29 Aug 2020 00:18:41
User entered 'No (N)'	System	29 Aug 2020 00:18:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '01a891c7-4d8a-46c7-a264-db18cf82471e'	System	29 Aug 2020 00:18:41
User entered 'No (N)'	System	29 Aug 2020 00:18:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '01a891c7-4d8a-46c7-a264-db18cf82471e'	System	29 Aug 2020 00:18:41
User entered 'None (1)'	System	29 Aug 2020 00:18:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '01a891c7-4d8a-46c7-a264-db18cf82471e'	System	29 Aug 2020 00:18:41
User entered '28 Aug 2020 20:18'	System	29 Aug 2020 00:18:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:38', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'None (0)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:44', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered 'No (N)'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T15:57:49', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '38dbfd76-ce51-4fe3-a951-bbbb113593aa'	System	22 Aug 2020 19:57:53
User entered '22 Aug 2020 15:57'	System	22 Aug 2020 19:57:53

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 15:39'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 18:09'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:18', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:29', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f' User entered 'None (0)'	System	23 Aug 2020 00:13:50
	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f'	System	23 Aug 2020 00:13:50
User entered 'No (N)'	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-22T20:12:43', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '142dee43-4f96-4879-af42-65daa6b3258f'	System	23 Aug 2020 00:13:50
User entered '22 Aug 2020 20:12'	System	23 Aug 2020 00:13:50

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Aug 2020 19:04'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 2'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:29', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:33', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:40', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:43', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'None (0)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:22:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered 'No (N)'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-23T19:23:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4e05116c-2006-4855-a375-2f8ca724f038'	System	23 Aug 2020 23:23:07
User entered '23 Aug 2020 19:23'	System	23 Aug 2020 23:23:07

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 3'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:33:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered 'None (0)'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:33:48', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af' User entered 'None (0)'	System	24 Aug 2020 23:34:41
	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:33:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered 'None (0)'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:34:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af' User entered 'None (0)'	System	24 Aug 2020 23:34:41
	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:34:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered 'None (0)'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:34:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered 'None (0)'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:34:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered 'No (N)'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-24T19:34:38', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e8700d22-9cc8-4c64-8f6b-823bae5558af'	System	24 Aug 2020 23:34:41
User entered '24 Aug 2020 19:34'	System	24 Aug 2020 23:34:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 4'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:20', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'None (0)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:47:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered 'No (N)'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-25T20:48:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '330a92c5-8a6f-4b44-b21c-3ef75b1c6860'	System	26 Aug 2020 00:48:05
User entered '25 Aug 2020 20:48'	System	26 Aug 2020 00:48:05

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 5'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:12', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:22', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'None (0)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered 'No (N)'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-26T19:45:40', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '75a83f3d-c2b1-4776-afec-f36da7abba22'	System	26 Aug 2020 23:45:44
User entered '26 Aug 2020 19:45'	System	26 Aug 2020 23:45:44

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 6'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:38', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:49', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:52:53', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'None (0)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:53:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered 'No (N)'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-27T20:53:06', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3b95bf5-1de1-4636-8819-352125013c97'	System	28 Aug 2020 00:53:09
User entered '27 Aug 2020 20:53'	System	28 Aug 2020 00:53:09

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 7'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:49', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:53', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:18:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:19:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:19:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:19:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'None (0)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:19:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered 'No (N)'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-08-28T20:19:29', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0376ed56-85d5-4a7f-befc-5139477a2bf1'	System	29 Aug 2020 00:19:36
User entered '28 Aug 2020 20:19'	System	29 Aug 2020 00:19:36

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 19:41:41

US3352213

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 19:13:06

US3352213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '29 Aug 2020'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 19:13:06

US3352213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 19:13:06

US3352213

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Rosaidaliz Carreira (b) (4)	29 Aug 2020 19:13:06

US3352213

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 19:13:15

US3352213

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:12
User entered 'I'	System	29 Aug 2020 19:13:15

US3352213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 17:27:48

US3352213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '05 Sep 2020'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 17:27:48

US3352213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 17:27:48

US3352213

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Rosaidaliz Carreira (b) (4)	05 Sep 2020 17:27:48

US3352213

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 17:28:04

US3352213

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User entered 'I'	System	05 Sep 2020 17:28:04

US3352213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 19:14:07

US3352213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12 Sep 2020'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 19:14:07

US3352213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 19:14:07

US3352213

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Rosaidaliz Carreira (b) (4)	14 Sep 2020 19:14:07

US3352213

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 19:14:19

US3352213

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:59:02
User entered 'I'	System	14 Sep 2020 19:14:19

US3352213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:28:31

US3352213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:28:31

US3352213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Sep 2020 17:28:31

US3352213

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'VISIT2'	System	19 Sep 2020 17:28:31

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:00'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.8' C	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '78'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'bpm'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '15'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'breaths/min'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '131'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'mmHg'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '75'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'mmHg'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '13:12'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered '19 Sep 2020 13:12'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.8' C	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '63'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'bpm'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'breaths/min'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '131'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'mmHg'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '82'	(b) (4), (b) (6)	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:44:56
User entered 'mmHg'	System	19 Sep 2020 17:30:44

US3352213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	19 Sep 2020 17:30:49

US3352213

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:30:49

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered 'MRNA-1273 OR PLACEBO'	System	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:42'	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered '19 Sep 2020 12:42'	System	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered 'ONCE'	System	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered 'INTRAMUSCULAR'	System	19 Sep 2020 17:18:14

US3352213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:31:09

US3352213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:31:09

US3352213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:09'	(b) (4), (b) (6)	19 Sep 2020 17:31:09

US3352213

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered '19 Sep 2020 12:09'	System	19 Sep 2020 17:31:09

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:02'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered empty.	System	19 Sep 2020 17:31:18

US3352213

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 17:31:21

US3352213

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:16
User entered 'I'	System	19 Sep 2020 17:31:21

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:19:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3085b3a-ad45-46ef-8c01-85644d485ebd'	System	19 Sep 2020 17:19:54
User entered 'Yes (Y)'	System	19 Sep 2020 17:19:54

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:19:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3085b3a-ad45-46ef-8c01-85644d485ebd'	System	19 Sep 2020 17:19:54
User entered '98.3'	System	19 Sep 2020 17:19:54

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:19:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3085b3a-ad45-46ef-8c01-85644d485ebd'	System	19 Sep 2020 17:19:54
User entered 'No (N)'	System	19 Sep 2020 17:19:54

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:19:49', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f3085b3a-ad45-46ef-8c01-85644d485ebd'	System	19 Sep 2020 17:19:54
User entered '19 Sep 2020 13:19'	System	19 Sep 2020 17:19:54

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 15:32'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:52:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb8abd9e-e449-4d0a-bdc6-b73d8b46c0e1'	System	19 Sep 2020 23:52:58
User entered 'Yes (Y)'	System	19 Sep 2020 23:52:58

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:52:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb8abd9e-e449-4d0a-bdc6-b73d8b46c0e1'	System	19 Sep 2020 23:52:58
User entered '98.5'	System	19 Sep 2020 23:52:58

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:52:43', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb8abd9e-e449-4d0a-bdc6-b73d8b46c0e1'	System	19 Sep 2020 23:52:58
User entered 'No (N)'	System	19 Sep 2020 23:52:58

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:52:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb8abd9e-e449-4d0a-bdc6-b73d8b46c0e1'	System	19 Sep 2020 23:52:58
User entered '19 Sep 2020 19:52'	System	19 Sep 2020 23:52:58

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 16:27'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 2'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:01:50', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1b033c8c-3c17-4b6d-bd38-ce8c51609a40'	System	20 Sep 2020 23:02:08
User entered 'Yes (Y)'	System	20 Sep 2020 23:02:08

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:01:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1b033c8c-3c17-4b6d-bd38-ce8c51609a40'	System	20 Sep 2020 23:02:08
User entered '98.7'	System	20 Sep 2020 23:02:08

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:01', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1b033c8c-3c17-4b6d-bd38-ce8c51609a40'	System	20 Sep 2020 23:02:08
User entered 'No (N)'	System	20 Sep 2020 23:02:08

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:05', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1b033c8c-3c17-4b6d-bd38-ce8c51609a40'	System	20 Sep 2020 23:02:08
User entered '20 Sep 2020 19:02'	System	20 Sep 2020 23:02:08

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 3'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:31:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3ad227aa-7f93-4d80-851d-835be0666477'	System	21 Sep 2020 23:33:10
User entered 'Yes (Y)'	System	21 Sep 2020 23:33:10

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:32:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3ad227aa-7f93-4d80-851d-835be0666477'	System	21 Sep 2020 23:33:10
User entered '98.7'	System	21 Sep 2020 23:33:10

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:32:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3ad227aa-7f93-4d80-851d-835be0666477'	System	21 Sep 2020 23:33:10
User entered 'No (N)'	System	21 Sep 2020 23:33:10

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3ad227aa-7f93-4d80-851d-835be0666477'	System	21 Sep 2020 23:33:10
User entered '21 Sep 2020 19:33'	System	21 Sep 2020 23:33:10

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 4'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:01', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8576b-0459-4489-8f7d-ffe669a6679b'	System	23 Sep 2020 00:05:39
User entered 'Yes (Y)'	System	23 Sep 2020 00:05:39

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:13', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8576b-0459-4489-8f7d-ffe669a6679b'	System	23 Sep 2020 00:05:39
User entered '97.5'	System	23 Sep 2020 00:05:39

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8576b-0459-4489-8f7d-ffe669a6679b'	System	23 Sep 2020 00:05:39
User entered 'No (N)'	System	23 Sep 2020 00:05:39

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8576b-0459-4489-8f7d-ffe669a6679b'	System	23 Sep 2020 00:05:39
User entered '22 Sep 2020 20:05'	System	23 Sep 2020 00:05:39

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 5'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:02:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '479f3c19-cccc-415b-9a2d-cfc83b0b1b24'	System	23 Sep 2020 23:03:30
User entered 'Yes (Y)'	System	23 Sep 2020 23:03:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '479f3c19-cccc-415b-9a2d-cfc83b0b1b24'	System	23 Sep 2020 23:03:30
User entered '97.5'	System	23 Sep 2020 23:03:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '479f3c19-cccc-415b-9a2d-cfc83b0b1b24'	System	23 Sep 2020 23:03:30
User entered 'No (N)'	System	23 Sep 2020 23:03:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '479f3c19-cccc-415b-9a2d-cfc83b0b1b24'	System	23 Sep 2020 23:03:30
User entered '23 Sep 2020 19:03'	System	23 Sep 2020 23:03:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 6'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:08:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b4630da2-7982-45b8-bcd2-d7b155697136'	System	24 Sep 2020 23:09:30
User entered 'Yes (Y)'	System	24 Sep 2020 23:09:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b4630da2-7982-45b8-bcd2-d7b155697136'	System	24 Sep 2020 23:09:30
User entered '97.4'	System	24 Sep 2020 23:09:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:18', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b4630da2-7982-45b8-bcd2-d7b155697136'	System	24 Sep 2020 23:09:30
User entered 'No (N)'	System	24 Sep 2020 23:09:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:23', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b4630da2-7982-45b8-bcd2-d7b155697136'	System	24 Sep 2020 23:09:30
User entered '24 Sep 2020 19:09'	System	24 Sep 2020 23:09:30

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 7'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd0e2f0d0-395c-421e-8161-86db97e50cfc'	System	25 Sep 2020 23:57:41
User entered 'Yes (Y)'	System	25 Sep 2020 23:57:41

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd0e2f0d0-395c-421e-8161-86db97e50cfc'	System	25 Sep 2020 23:57:41
User entered '97.5'	System	25 Sep 2020 23:57:41

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:33', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd0e2f0d0-395c-421e-8161-86db97e50cfc'	System	25 Sep 2020 23:57:41
User entered 'No (N)'	System	25 Sep 2020 23:57:41

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd0e2f0d0-395c-421e-8161-86db97e50cfc'	System	25 Sep 2020 23:57:41
User entered '25 Sep 2020 19:57'	System	25 Sep 2020 23:57:41

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4cdee726-2636-45e0-b348-44c446f20c98'	System	19 Sep 2020 17:20:50
User entered 'None (1)'	System	19 Sep 2020 17:20:50

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4cdee726-2636-45e0-b348-44c446f20c98'	System	19 Sep 2020 17:20:50
User entered 'No (N)'	System	19 Sep 2020 17:20:50

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4cdee726-2636-45e0-b348-44c446f20c98'	System	19 Sep 2020 17:20:50
User entered 'No (N)'	System	19 Sep 2020 17:20:50

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4cdee726-2636-45e0-b348-44c446f20c98'	System	19 Sep 2020 17:20:50
User entered 'None (1)'	System	19 Sep 2020 17:20:50

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4cdee726-2636-45e0-b348-44c446f20c98'	System	19 Sep 2020 17:20:50
User entered '19 Sep 2020 13:20'	System	19 Sep 2020 17:20:50

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 15:32'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:53:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '94a41b35-ac4c-43d8-b897-73c7a3130aea'	System	19 Sep 2020 23:53:52
User entered 'None (1)'	System	19 Sep 2020 23:53:52

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:53:18', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '94a41b35-ac4c-43d8-b897-73c7a3130aea'	System	19 Sep 2020 23:53:52
User entered 'No (N)'	System	19 Sep 2020 23:53:52

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:53:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '94a41b35-ac4c-43d8-b897-73c7a3130aea'	System	19 Sep 2020 23:53:52
User entered 'No (N)'	System	19 Sep 2020 23:53:52

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:53:45', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '94a41b35-ac4c-43d8-b897-73c7a3130aea'	System	19 Sep 2020 23:53:52
User entered 'None (1)'	System	19 Sep 2020 23:53:52

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:53:50', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '94a41b35-ac4c-43d8-b897-73c7a3130aea'	System	19 Sep 2020 23:53:52
User entered '19 Sep 2020 19:53'	System	19 Sep 2020 23:53:52

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 16:27'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 2'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eb796f84-279e-4a5b-972b-cd50fe4d041e'	System	20 Sep 2020 23:02:37
User entered 'None (1)'	System	20 Sep 2020 23:02:37

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eb796f84-279e-4a5b-972b-cd50fe4d041e'	System	20 Sep 2020 23:02:37
User entered 'No (N)'	System	20 Sep 2020 23:02:37

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eb796f84-279e-4a5b-972b-cd50fe4d041e'	System	20 Sep 2020 23:02:37
User entered 'No (N)'	System	20 Sep 2020 23:02:37

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eb796f84-279e-4a5b-972b-cd50fe4d041e'	System	20 Sep 2020 23:02:37
User entered 'None (1)'	System	20 Sep 2020 23:02:37

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eb796f84-279e-4a5b-972b-cd50fe4d041e'	System	20 Sep 2020 23:02:37
User entered '20 Sep 2020 19:02'	System	20 Sep 2020 23:02:37

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 3'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a8eba43b-66c7-406f-a039-b071157494a3'	System	21 Sep 2020 23:33:57
User entered 'None (1)'	System	21 Sep 2020 23:33:57

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a8eba43b-66c7-406f-a039-b071157494a3'	System	21 Sep 2020 23:33:57
User entered 'No (N)'	System	21 Sep 2020 23:33:57

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:40', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a8eba43b-66c7-406f-a039-b071157494a3'	System	21 Sep 2020 23:33:57
User entered 'No (N)'	System	21 Sep 2020 23:33:57

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a8eba43b-66c7-406f-a039-b071157494a3'	System	21 Sep 2020 23:33:57
User entered 'None (1)'	System	21 Sep 2020 23:33:57

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:33:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'a8eba43b-66c7-406f-a039-b071157494a3'	System	21 Sep 2020 23:33:57
User entered '21 Sep 2020 19:33'	System	21 Sep 2020 23:33:57

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 4'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'c96b8801-d0be-4d0d-bc10-784408aa404f'	System	23 Sep 2020 00:06:21
User entered 'None (1)'	System	23 Sep 2020 00:06:21

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:05:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'c96b8801-d0be-4d0d-bc10-784408aa404f'	System	23 Sep 2020 00:06:21
User entered 'No (N)'	System	23 Sep 2020 00:06:21

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'c96b8801-d0be-4d0d-bc10-784408aa404f'	System	23 Sep 2020 00:06:21
User entered 'No (N)'	System	23 Sep 2020 00:06:21

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'c96b8801-d0be-4d0d-bc10-784408aa404f'	System	23 Sep 2020 00:06:21
User entered 'None (1)'	System	23 Sep 2020 00:06:21

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'c96b8801-d0be-4d0d-bc10-784408aa404f'	System	23 Sep 2020 00:06:21
User entered '22 Sep 2020 20:06'	System	23 Sep 2020 00:06:21

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 5'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:38', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e98cd949-3f67-45f1-9b63-e4b46000ec21'	System	23 Sep 2020 23:04:12
User entered 'None (1)'	System	23 Sep 2020 23:04:12

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:44', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e98cd949-3f67-45f1-9b63-e4b46000ec21'	System	23 Sep 2020 23:04:12
User entered 'No (N)'	System	23 Sep 2020 23:04:12

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:03:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e98cd949-3f67-45f1-9b63-e4b46000ec21'	System	23 Sep 2020 23:04:12
User entered 'No (N)'	System	23 Sep 2020 23:04:12

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e98cd949-3f67-45f1-9b63-e4b46000ec21'	System	23 Sep 2020 23:04:12
User entered 'None (1)'	System	23 Sep 2020 23:04:12

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e98cd949-3f67-45f1-9b63-e4b46000ec21'	System	23 Sep 2020 23:04:12
User entered '23 Sep 2020 19:04'	System	23 Sep 2020 23:04:12

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 6'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '27727b10-dccc-464b-a5ba-6262eafb8a3f'	System	24 Sep 2020 23:10:08
User entered 'None (1)'	System	24 Sep 2020 23:10:08

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '27727b10-dccc-464b-a5ba-6262eafb8a3f'	System	24 Sep 2020 23:10:08
User entered 'No (N)'	System	24 Sep 2020 23:10:08

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:09:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '27727b10-dccc-464b-a5ba-6262eafb8a3f'	System	24 Sep 2020 23:10:08
User entered 'No (N)'	System	24 Sep 2020 23:10:08

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '27727b10-dccc-464b-a5ba-6262eafb8a3f'	System	24 Sep 2020 23:10:08
User entered 'None (1)'	System	24 Sep 2020 23:10:08

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '27727b10-dccc-464b-a5ba-6262eafb8a3f' User entered '24 Sep 2020 19:10'	System	24 Sep 2020 23:10:08
	System	24 Sep 2020 23:10:08

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 7'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ac1cd814-cd8b-4936-b0fe-d6de83dd0164'	System	25 Sep 2020 23:58:32
User entered 'None (1)'	System	25 Sep 2020 23:58:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:57:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ac1cd814-cd8b-4936-b0fe-d6de83dd0164'	System	25 Sep 2020 23:58:32
User entered 'No (N)'	System	25 Sep 2020 23:58:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ac1cd814-cd8b-4936-b0fe-d6de83dd0164'	System	25 Sep 2020 23:58:32
User entered 'No (N)'	System	25 Sep 2020 23:58:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ac1cd814-cd8b-4936-b0fe-d6de83dd0164'	System	25 Sep 2020 23:58:32
User entered 'None (1)'	System	25 Sep 2020 23:58:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:28', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ac1cd814-cd8b-4936-b0fe-d6de83dd0164'	System	25 Sep 2020 23:58:32
User entered '25 Sep 2020 19:58'	System	25 Sep 2020 23:58:32

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:20:59', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:18', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'None (0)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered 'No (N)'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T13:21:28', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '08f4bc93-dba8-4e11-8b71-f6d7d167ac66'	System	19 Sep 2020 17:21:31
User entered '19 Sep 2020 13:21'	System	19 Sep 2020 17:21:31

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 13:02'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 15:32'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:06', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'None (0)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered 'No (N)'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-19T19:54:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e2fd21ac-9a14-4b0b-8cfa-e8401b86b525'	System	19 Sep 2020 23:55:01
User entered '19 Sep 2020 19:54'	System	19 Sep 2020 23:55:01

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '19 Sep 2020 16:27'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 2'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:44', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'None (0)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:49', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'None (0)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'None (0)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:02:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb' User entered 'None (0)'	System	20 Sep 2020 23:03:13
	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:03:01', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'None (0)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:03:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'None (0)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:03:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb'	System	20 Sep 2020 23:03:13
User entered 'No (N)'	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-20T19:03:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3f11013c-b109-4006-8540-985dd2b9d1eb' User entered '20 Sep 2020 19:03'	System	20 Sep 2020 23:03:13
	System	20 Sep 2020 23:03:13

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 3'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d' User entered 'None (0)'	System	21 Sep 2020 23:34:53
	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d'	System	21 Sep 2020 23:34:53
User entered 'None (0)'	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d' User entered 'None (0)'	System	21 Sep 2020 23:34:53
	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:25', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d' User entered 'None (0)'	System	21 Sep 2020 23:34:53
	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d' User entered 'None (0)'	System	21 Sep 2020 23:34:53
	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:39', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d'	System	21 Sep 2020 23:34:53
User entered 'None (0)'	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d'	System	21 Sep 2020 23:34:53
User entered 'No (N)'	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-21T19:34:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '58ac5371-a305-429a-b9a6-14f12c0dc82d'	System	21 Sep 2020 23:34:53
User entered '21 Sep 2020 19:34'	System	21 Sep 2020 23:34:53

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 4'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:35', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:53', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:06:57', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'None (0)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:07:05', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered 'No (N)'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-22T20:07:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd72dd1ea-c2c1-4bd4-b27f-c857e3a87dc6'	System	23 Sep 2020 00:07:11
User entered '22 Sep 2020 20:07'	System	23 Sep 2020 00:07:11

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 5'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f'	System	23 Sep 2020 23:05:02
User entered 'None (0)'	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'None (0)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'None (0)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'None (0)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:36', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'None (0)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'None (0)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered 'No (N)'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-23T19:04:59', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1493332e-bc13-4383-b16c-4051e9089c2f' User entered '23 Sep 2020 19:04'	System	23 Sep 2020 23:05:02
	System	23 Sep 2020 23:05:02

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 6'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:33', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'None (0)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered 'No (N)'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-24T19:10:50', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '4c7556bb-89c6-4946-bc6b-47edd7a4c32a'	System	24 Sep 2020 23:10:52
User entered '24 Sep 2020 19:10'	System	24 Sep 2020 23:10:52

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	19 Sep 2020 17:18:14
User entered 'Day 7'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:34', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:48', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:58:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:59:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'None (0)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:59:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered 'No (N)'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-09-25T19:59:12', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'd4d117a2-b95e-4462-8514-a26559653062'	System	25 Sep 2020 23:59:15
User entered '25 Sep 2020 19:59'	System	25 Sep 2020 23:59:15

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 17:18:14

US3352213

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:11:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 17:18:14

US3352213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:29:02

US3352213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:29:02

US3352213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 17:29:02

US3352213

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:29:02

US3352213

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:29:13

US3352213

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:44
User entered 'I'	System	28 Sep 2020 17:29:13

US3352213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 19:05:26

US3352213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '3 Oct 2020'	(b) (4), (b) (6)	03 Oct 2020 19:05:26

US3352213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Oct 2020 19:05:26

US3352213

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	03 Oct 2020 19:05:26

US3352213

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 19:05:30

US3352213

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:33
User entered 'I'	System	03 Oct 2020 19:05:30

US3352213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:43:37

US3352213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '10 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 15:43:37

US3352213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Oct 2020 15:43:37

US3352213

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 15:43:37

US3352213

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 15:43:48

US3352213

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:58:25
User entered 'I'	System	10 Oct 2020 15:43:48

US3352213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	17 Oct 2020 14:02:41

US3352213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	17 Oct 2020 14:02:41

US3352213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	17 Oct 2020 14:02:41

US3352213

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered 'VISIT3'	System	17 Oct 2020 14:02:41

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '09:30'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered '17 Oct 2020 09:30'	System	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '37.1' C	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '82'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered 'bpm'	System	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered 'breaths/min'	System	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '137'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered 'mmHg'	System	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '79'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered 'mmHg'	System	17 Oct 2020 14:03:27

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:22:02

US3352213

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:22:02

US3352213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:34

US3352213

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Matthew Muniz (b) (4)	17 Oct 2020 14:03:34

US3352213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:59

US3352213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '17 Oct 2020'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:59

US3352213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '09:40'	Matthew Muniz (b) (4)	17 Oct 2020 14:03:59

US3352213

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered '17 Oct 2020 09:40'	System	17 Oct 2020 14:03:59

US3352213

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	17 Oct 2020 14:04:03

US3352213

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:02
User entered '1'	System	17 Oct 2020 14:04:03

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 64'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-24T11:35:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8061d-39e4-4114-8978-aac7c9aae021'	System	24 Oct 2020 15:35:55
User entered 'No (N)'	System	24 Oct 2020 15:35:55

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-24T11:35:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8061d-39e4-4114-8978-aac7c9aae021'	System	24 Oct 2020 15:35:55
User entered 'No (N)'	System	24 Oct 2020 15:35:55

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-24T11:35:52', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3cd8061d-39e4-4114-8978-aac7c9aae021' User entered '24 Oct 2020 11:35:52'	System	24 Oct 2020 15:35:55
	System	24 Oct 2020 15:35:55

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 71'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-31T19:46:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'aefe6869-b3ab-4eaa-ad1b-6c4330aa2022'	System	31 Oct 2020 23:46:49
User entered 'No (N)'	System	31 Oct 2020 23:46:49

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-31T19:46:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'aefe6869-b3ab-4eaa-ad1b-6c4330aa2022'	System	31 Oct 2020 23:46:49
User entered 'No (N)'	System	31 Oct 2020 23:46:49

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-10-31T19:46:45', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'aefe6869-b3ab-4eaa-ad1b-6c4330aa2022'	System	31 Oct 2020 23:46:49
User entered '31 Oct 2020 19:46:45'	System	31 Oct 2020 23:46:49

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 78'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-05T12:51:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ff625fb7-0f9a-4718-9909-2597bc301aa4'	System	05 Nov 2020 17:52:07
User entered 'No (N)'	System	05 Nov 2020 17:52:07

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-05T12:51:57', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ff625fb7-0f9a-4718-9909-2597bc301aa4'	System	05 Nov 2020 17:52:07
User entered 'No (N)'	System	05 Nov 2020 17:52:07

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-05T12:52:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ff625fb7-0f9a-4718-9909-2597bc301aa4'	System	05 Nov 2020 17:52:07
User entered '05 Nov 2020 12:52:00'	System	05 Nov 2020 17:52:07

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered 'Day 92'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-19T15:42:23', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e4f3c0ce-ae06-4de9-b9b3-522b010c194b'	System	19 Nov 2020 20:42:57
User entered 'No (N)'	System	19 Nov 2020 20:42:57

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-19T15:42:32', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e4f3c0ce-ae06-4de9-b9b3-522b010c194b'	System	19 Nov 2020 20:42:57
User entered 'No (N)'	System	19 Nov 2020 20:42:57

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-19T15:42:53', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'e4f3c0ce-ae06-4de9-b9b3-522b010c194b'	System	19 Nov 2020 20:42:57
User entered '19 Nov 2020 15:42:53'	System	19 Nov 2020 20:42:57

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 19:41:41

US3352213

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:42:29
Data entry locked.	System	22 Aug 2020 19:41:41
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 19:41:41

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2020-11-23T17:40:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eda9a951-18d4-464f-8ed9-139b4f2b2169'	System	23 Nov 2020 22:40:21
User entered 'No (N)'	System	23 Nov 2020 22:40:21

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2020-11-23T17:40:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eda9a951-18d4-464f-8ed9-139b4f2b2169'	System	23 Nov 2020 22:40:21
User entered 'No (N)'	System	23 Nov 2020 22:40:21

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-11-23T17:40:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'eda9a951-18d4-464f-8ed9-139b4f2b2169' User entered '23 Nov 2020 17:40:17'	System	23 Nov 2020 22:40:21
	System	23 Nov 2020 22:40:21

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2020-12-02T20:19:12', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '53e59388-83bb-4f49-931c-d966510c9ddf'	System	03 Dec 2020 01:19:29
User entered 'No (N)'	System	03 Dec 2020 01:19:29

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2020-12-02T20:19:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '53e59388-83bb-4f49-931c-d966510c9ddf'	System	03 Dec 2020 01:19:29
User entered 'No (N)'	System	03 Dec 2020 01:19:29

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-12-02T20:19:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '53e59388-83bb-4f49-931c-d966510c9ddf' User entered '02 Dec 2020 20:19:26'	System	03 Dec 2020 01:19:29
	System	03 Dec 2020 01:19:29

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2020-12-09T12:03:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '5bd0215a-2892-41e1-b560-adf42f01d151'	System	09 Dec 2020 17:03:53
User entered 'No (N)'	System	09 Dec 2020 17:03:53

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2020-12-09T12:03:22', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '5bd0215a-2892-41e1-b560-adf42f01d151'	System	09 Dec 2020 17:03:53
User entered 'No (N)'	System	09 Dec 2020 17:03:53

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-12-09T12:03:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '5bd0215a-2892-41e1-b560-adf42f01d151'	System	09 Dec 2020 17:03:53
User entered '09 Dec 2020 12:03:37'	System	09 Dec 2020 17:03:53

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2020-12-22T14:37:36', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'dfb8ed55-41b1-4138-bb8b-60a3e8b9548e'	System	22 Dec 2020 19:37:57
User entered 'No (N)'	System	22 Dec 2020 19:37:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2020-12-22T14:37:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'dfb8ed55-41b1-4138-bb8b-60a3e8b9548e'	System	22 Dec 2020 19:37:57
User entered 'No (N)'	System	22 Dec 2020 19:37:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2020-12-22T14:37:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'dfb8ed55-41b1-4138-bb8b-60a3e8b9548e' User entered '22 Dec 2020 14:37:51'	System	22 Dec 2020 19:37:57
	System	22 Dec 2020 19:37:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2021-01-01T12:19:59', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1761fa87-d446-42b1-b6dc-5f7a8842dea2'	System	01 Jan 2021 17:20:18
User entered 'No (N)'	System	01 Jan 2021 17:20:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2021-01-01T12:20:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1761fa87-d446-42b1-b6dc-5f7a8842dea2'	System	01 Jan 2021 17:20:18
User entered 'No (N)'	System	01 Jan 2021 17:20:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2021-01-01T12:20:12', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1761fa87-d446-42b1-b6dc-5f7a8842dea2'	System	01 Jan 2021 17:20:18
User entered '01 Jan 2021 12:20:12'	System	01 Jan 2021 17:20:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2021-01-05T07:39:56', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ba18d6e7-60ef-48f6-9703-aa4ede535413'	System	05 Jan 2021 12:40:08
User entered 'No (N)'	System	05 Jan 2021 12:40:08

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2021-01-05T07:39:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ba18d6e7-60ef-48f6-9703-aa4ede535413'	System	05 Jan 2021 12:40:08
User entered 'No (N)'	System	05 Jan 2021 12:40:08

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2021-01-05T07:40:02', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ba18d6e7-60ef-48f6-9703-aa4ede535413' User entered '05 Jan 2021 07:40:02'	System	05 Jan 2021 12:40:08
	System	05 Jan 2021 12:40:08

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (1454df1b9226f10e)', Time: '2021-01-12T08:37:28', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb4c0391-c89e-421c-bc68-f2cfc3f13283'	System	12 Jan 2021 13:37:50
User entered 'No (N)'	System	12 Jan 2021 13:37:50

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (1454df1b9226f10e)', Time: '2021-01-12T08:37:33', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb4c0391-c89e-421c-bc68-f2cfc3f13283'	System	12 Jan 2021 13:37:50
User entered 'No (N)'	System	12 Jan 2021 13:37:50

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1454df1b9226f10e)', Time: '2021-01-12T08:37:43', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'fb4c0391-c89e-421c-bc68-f2cfc3f13283' User entered '12 Jan 2021 08:37:43'	System	12 Jan 2021 13:37:50
	System	12 Jan 2021 13:37:50

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-01-19T14:56:58', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8c4d1b38-da0c-4a0e-a824-5b908616b373'	System	19 Jan 2021 19:57:25
User entered 'No (N)'	System	19 Jan 2021 19:57:25

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-01-19T14:57:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8c4d1b38-da0c-4a0e-a824-5b908616b373'	System	19 Jan 2021 19:57:25
User entered 'No (N)'	System	19 Jan 2021 19:57:25

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-01-19T14:57:19', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '8c4d1b38-da0c-4a0e-a824-5b908616b373'	System	19 Jan 2021 19:57:25
User entered '19 Jan 2021 14:57:19'	System	19 Jan 2021 19:57:25

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-01-25T11:09:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '32169e71-2f94-4a49-a4c1-5c227977bb6e'	System	25 Jan 2021 16:10:03
User entered 'No (N)'	System	25 Jan 2021 16:10:03

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-01-25T11:09:33', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '32169e71-2f94-4a49-a4c1-5c227977bb6e'	System	25 Jan 2021 16:10:03
User entered 'No (N)'	System	25 Jan 2021 16:10:03

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-01-25T11:09:57', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '32169e71-2f94-4a49-a4c1-5c227977bb6e' User entered '25 Jan 2021 11:09:57'	System	25 Jan 2021 16:10:03
	System	25 Jan 2021 16:10:03

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-02-02T17:14:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '76a372aa-2dc4-40d1-9e9d-397758f58e2b'	System	02 Feb 2021 22:14:47
User entered 'No (N)'	System	02 Feb 2021 22:14:47

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-02-02T17:14:26', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '76a372aa-2dc4-40d1-9e9d-397758f58e2b'	System	02 Feb 2021 22:14:47
User entered 'No (N)'	System	02 Feb 2021 22:14:47

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-02T17:14:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '76a372aa-2dc4-40d1-9e9d-397758f58e2b' User entered '02 Feb 2021 17:14:41'	System	02 Feb 2021 22:14:47
	System	02 Feb 2021 22:14:47

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-02-09T09:37:40', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1e011d48-e440-43f2-a870-dacc9d245006'	System	09 Feb 2021 14:37:51
User entered 'No (N)'	System	09 Feb 2021 14:37:51

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-02-09T09:37:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1e011d48-e440-43f2-a870-dacc9d245006'	System	09 Feb 2021 14:37:51
User entered 'No (N)'	System	09 Feb 2021 14:37:51

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-09T09:37:45', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '1e011d48-e440-43f2-a870-dacc9d245006'	System	09 Feb 2021 14:37:51
User entered '09 Feb 2021 09:37:45'	System	09 Feb 2021 14:37:51

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-02-16T08:38:11', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ada00c8b-a746-4ba3-b084-472281bb1665'	System	16 Feb 2021 13:38:22
User entered 'No (N)'	System	16 Feb 2021 13:38:22

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-02-16T08:38:13', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ada00c8b-a746-4ba3-b084-472281bb1665'	System	16 Feb 2021 13:38:22
User entered 'No (N)'	System	16 Feb 2021 13:38:22

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-16T08:38:17', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'ada00c8b-a746-4ba3-b084-472281bb1665'	System	16 Feb 2021 13:38:22
User entered '16 Feb 2021 08:38:17'	System	16 Feb 2021 13:38:22

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-02-22T09:07:45', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '247c9302-efc5-4dc6-a214-ab74c46a0652'	System	22 Feb 2021 14:08:18
User entered 'No (N)'	System	22 Feb 2021 14:08:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-02-22T09:07:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '247c9302-efc5-4dc6-a214-ab74c46a0652'	System	22 Feb 2021 14:08:18
User entered 'No (N)'	System	22 Feb 2021 14:08:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-22T09:08:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '247c9302-efc5-4dc6-a214-ab74c46a0652'	System	22 Feb 2021 14:08:18
User entered '22 Feb 2021 09:08:14'	System	22 Feb 2021 14:08:18

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-03-02T13:01:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0a0a65c5-3974-4b66-a94c-4b1f6738a131'	System	02 Mar 2021 18:05:28
User entered 'No (N)'	System	02 Mar 2021 18:05:28

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-03-02T13:01:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0a0a65c5-3974-4b66-a94c-4b1f6738a131'	System	02 Mar 2021 18:05:28
User entered 'No (N)'	System	02 Mar 2021 18:05:28

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-03-02T13:01:51', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0a0a65c5-3974-4b66-a94c-4b1f6738a131'	System	02 Mar 2021 18:05:28
User entered '02 Mar 2021 13:01:51'	System	02 Mar 2021 18:05:28

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-03-08T12:00:37', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'cef2e189-0f5b-487a-838c-27689787fb3c'	System	08 Mar 2021 17:02:54
User entered 'No (N)'	System	08 Mar 2021 17:02:54

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-03-08T12:00:41', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'cef2e189-0f5b-487a-838c-27689787fb3c'	System	08 Mar 2021 17:02:54
User entered 'No (N)'	System	08 Mar 2021 17:02:54

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-03-08T12:00:54', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'cef2e189-0f5b-487a-838c-27689787fb3c' User entered '08 Mar 2021 12:00:54'	System	08 Mar 2021 17:02:54
	System	08 Mar 2021 17:02:54

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-03-15T19:24:47', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '12793bd8-9fb9-45f6-a7d0-46b5147dc185'	System	15 Mar 2021 23:25:20
User entered 'No (N)'	System	15 Mar 2021 23:25:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-03-15T19:25:07', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '12793bd8-9fb9-45f6-a7d0-46b5147dc185'	System	15 Mar 2021 23:25:20
User entered 'No (N)'	System	15 Mar 2021 23:25:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-03-15T19:25:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '12793bd8-9fb9-45f6-a7d0-46b5147dc185'	System	15 Mar 2021 23:25:20
User entered '15 Mar 2021 19:25:16'	System	15 Mar 2021 23:25:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-03-23T12:09:55', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bd243a20-3892-4c7c-8043-ef85c113830c'	System	23 Mar 2021 16:13:31
User entered 'No (N)'	System	23 Mar 2021 16:13:31

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-03-23T12:10:00', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bd243a20-3892-4c7c-8043-ef85c113830c'	System	23 Mar 2021 16:13:31
User entered 'No (N)'	System	23 Mar 2021 16:13:31

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-03-23T12:10:08', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bd243a20-3892-4c7c-8043-ef85c113830c'	System	23 Mar 2021 16:13:31
User entered '23 Mar 2021 12:10:08'	System	23 Mar 2021 16:13:31

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-03-29T21:10:03', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f0f4591e-bdfd-4be9-9b14-2c286788c46c'	System	30 Mar 2021 01:16:15
User entered 'No (N)'	System	30 Mar 2021 01:16:15

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-03-29T21:10:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f0f4591e-bdfd-4be9-9b14-2c286788c46c'	System	30 Mar 2021 01:16:15
User entered 'No (N)'	System	30 Mar 2021 01:16:15

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-03-29T21:10:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'f0f4591e-bdfd-4be9-9b14-2c286788c46c'	System	30 Mar 2021 01:16:15
User entered '29 Mar 2021 21:10:21'	System	30 Mar 2021 01:16:15

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-04-05T19:13:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3c00f35f-88c8-498f-92b7-f96eae2177d'	System	05 Apr 2021 23:13:46
User entered 'No (N)'	System	05 Apr 2021 23:13:46

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-04-05T19:13:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3c00f35f-88c8-498f-92b7-f96eae2177d'	System	05 Apr 2021 23:13:46
User entered 'No (N)'	System	05 Apr 2021 23:13:46

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-04-05T19:13:42', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '3c00f35f-88c8-498f-92b7-f96eae2177d' User entered '05 Apr 2021 19:13:42'	System	05 Apr 2021 23:13:46
	System	05 Apr 2021 23:13:46

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-04-12T14:47:05', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b80022f5-abf5-42e4-8ad2-3408d558a77f'	System	12 Apr 2021 18:47:20
User entered 'No (N)'	System	12 Apr 2021 18:47:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-04-12T14:47:09', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b80022f5-abf5-42e4-8ad2-3408d558a77f'	System	12 Apr 2021 18:47:20
User entered 'No (N)'	System	12 Apr 2021 18:47:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-04-12T14:47:14', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'b80022f5-abf5-42e4-8ad2-3408d558a77f'	System	12 Apr 2021 18:47:20
User entered '12 Apr 2021 14:47:14'	System	12 Apr 2021 18:47:20

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-04-20T10:30:04', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6eb06e44-e181-40f1-88e3-42981918a1a0'	System	20 Apr 2021 14:30:37
User entered 'No (N)'	System	20 Apr 2021 14:30:37

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-04-20T10:30:10', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6eb06e44-e181-40f1-88e3-42981918a1a0'	System	20 Apr 2021 14:30:37
User entered 'No (N)'	System	20 Apr 2021 14:30:37

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-04-20T10:30:15', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '6eb06e44-e181-40f1-88e3-42981918a1a0'	System	20 Apr 2021 14:30:37
User entered '20 Apr 2021 10:30:15'	System	20 Apr 2021 14:30:37

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-04-26T21:25:16', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bc6437f1-7148-45ef-8b76-9dd03dd6e9e9'	System	27 Apr 2021 01:25:38
User entered 'No (N)'	System	27 Apr 2021 01:25:38

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-04-26T21:25:23', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bc6437f1-7148-45ef-8b76-9dd03dd6e9e9'	System	27 Apr 2021 01:25:38
User entered 'No (N)'	System	27 Apr 2021 01:25:38

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-04-26T21:25:30', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: 'bc6437f1-7148-45ef-8b76-9dd03dd6e9e9'	System	27 Apr 2021 01:25:38
User entered '26 Apr 2021 21:25:30'	System	27 Apr 2021 01:25:38

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[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 (c65bca6b42ac1b02)', Time: '2021-05-03T09:56:21', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0d64568e-988d-468b-abb1-0bbb542205d6'	System	03 May 2021 13:56:35
User entered 'No (N)'	System	03 May 2021 13:56:35

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

Have you been exposed to someone with 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 (c65bca6b42ac1b02)', Time: '2021-05-03T09:56:24', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0d64568e-988d-468b-abb1-0bbb542205d6'	System	03 May 2021 13:56:35
User entered 'No (N)'	System	03 May 2021 13:56:35

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-05-03T09:56:27', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0d64568e-988d-468b-abb1-0bbb542205d6'	System	03 May 2021 13:56:35
User entered '03 May 2021 09:56:27'	System	03 May 2021 13:56:35

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:20:57

US3352213

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:57
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:20:57

US3352213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:19

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)	26 Apr 2021 05:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-28T13:29:31', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0c84d505-acb7-4ed1-8918-eaf47b340bc6'	System	28 Feb 2021 18:29:57
User entered 'Yes (Y)'	System	28 Feb 2021 18:29:57

US3352213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:19

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-28T13:29:36', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0c84d505-acb7-4ed1-8918-eaf47b340bc6'	System	28 Feb 2021 18:29:57
User entered 'Yes (Y)'	System	28 Feb 2021 18:29:57

US3352213

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:11:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c65bca6b42ac1b02)', Time: '2021-02-28T13:29:46', User OID: 'PatientReportedOutcome (US3352213)', ODM File OID: '0c84d505-acb7-4ed1-8918-eaf47b340bc6' User entered '28 Feb 2021 13:29:46'	System	28 Feb 2021 18:29:57
	System	28 Feb 2021 18:29:57

US3352213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 18:54:24

US3352213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 18:54:24

US3352213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 18:54:24

US3352213

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:54:24

US3352213

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 18:54:33

US3352213

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:22
User entered 'I'	System	13 Nov 2020 18:54:33

US3352213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 22:25:02

US3352213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 22:25:02

US3352213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 22:25:02

US3352213

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 22:25:02

US3352213

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 22:25:06

US3352213

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User entered 'I'	System	17 Dec 2020 22:25:06

US3352213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 20:07:12

US3352213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 20:07:12

US3352213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 20:07:12

US3352213

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 20:07:12

US3352213

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 20:08:09

US3352213

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User entered 'I'	System	02 Feb 2021 20:08:09

US3352213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:47:44

US3352213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 18:47:44

US3352213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 18:47:44

US3352213

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 18:47:44

US3352213

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:47:48

US3352213

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:17
User entered 'I'	System	17 Feb 2021 18:47:48

US3352213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:27

US3352213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '18 Mar 2021'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:27

US3352213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:27

US3352213

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'VISIT4'	System	18 Mar 2021 16:41:27

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '18 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:15'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered '18 Mar 2021 11:15'	System	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.8' C	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '73'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'bpm'	System	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'breaths/min'	System	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '145'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'mmHg'	System	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '89'	(b) (4), (b) (6)	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'mmHg'	System	31 Mar 2021 14:37:25

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15

US3352213

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15

US3352213

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:33

US3352213

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Matthew Muniz (b) (4)	18 Mar 2021 16:41:33

US3352213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:45

US3352213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '18 Mar 2021'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:45

US3352213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:31'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:45

US3352213

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered '18 Mar 2021 11:31'	System	18 Mar 2021 16:41:45

US3352213

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:39:17

US3352213

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:09:15
User entered 'I'	System	18 Mar 2021 16:39:17

US3352213

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	14 Apr 2021 19:16:43

US3352213

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14 Apr 2021'	Yulexis Amestoy (b) (4)	14 Apr 2021 19:16:43

US3352213

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	14 Apr 2021 19:16:43

US3352213

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Yulexis Amestoy (b) (4)	14 Apr 2021 19:16:43

US3352213

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	14 Apr 2021 19:16:48

US3352213

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:16:48

US3352213

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:40:38

US3352213

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:40:38

US3352213

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Jan 2021 18:40:38

US3352213

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

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 18:40:38

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:21:28

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:21:28

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:39:33
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:39:33
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '1'	System	16 Jan 2021 18:40:57

US3352213

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

Form: Unblinding

Generated On: 09 Jun 2021 17:11:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '1'	System	16 Jan 2021 18:40:57

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered empty.	System	16 Jan 2021 18:43:34
DataPoint set to visible.	System	16 Jan 2021 18:40:57

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered empty.	System	16 Jan 2021 18:43:34
DataPoint set to visible.	System	16 Jan 2021 18:40:57

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:30'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '16 Jan 2021 11:30'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.7' C	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '91'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'bpm'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '14'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'breaths/min'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '120'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'mmHg'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '75'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'mmHg'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered empty.	System	16 Jan 2021 18:43:34
DataPoint set to visible.	System	16 Jan 2021 18:40:57

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:36'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '16 Jan 2021 12:36'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.6' C	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '98'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'bpm'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '15'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'breaths/min'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '137'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'mmHg'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '86'	(b) (4), (b) (6)	16 Jan 2021 18:43:34

US3352213

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'mmHg'	System	16 Jan 2021 18:43:34

US3352213

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	(b) (4), (b) (6)	16 Jan 2021 18:43:44

US3352213

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:43:44

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'mRNA-1273'	System	16 Jan 2021 18:44:10
DataPoint set to visible.	System	16 Jan 2021 18:40:57

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12:06'	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '16 Jan 2021 12:06'	System	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'ONCE'	System	16 Jan 2021 18:44:10

US3352213

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

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'INTRAMUSCULAR'	System	16 Jan 2021 18:44:10

US3352213

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:44:42

US3352213

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:44:42

US3352213

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:53'	(b) (4), (b) (6)	16 Jan 2021 18:44:42

US3352213

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '16 Jan 2021 11:53'	System	16 Jan 2021 18:44:42

US3352213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:45:07

US3352213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 18:45:07

US3352213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:42'	(b) (4), (b) (6)	16 Jan 2021 18:45:07

US3352213

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered '16 Jan 2021 11:42'	System	16 Jan 2021 18:45:07

US3352213

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 18:45:11

US3352213

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

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:30:38
User entered 'I'	System	16 Jan 2021 18:45:11

US3352213

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:20:20

US3352213

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '23 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 20:20:20

US3352213

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	24 Feb 2021 20:20:20

US3352213

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Three attempts made. subject did not answer.'	(b) (4), (b) (6)	24 Feb 2021 20:20:20

US3352213

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:20:26

US3352213

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User entered 'I'	System	24 Feb 2021 20:20:26

US3352213

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:24
User entered '1'	System	24 Feb 2021 20:20:26
DataPoint set to visible.	System	24 Feb 2021 20:20:26

US3352213

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:20:38

US3352213

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:20:38

US3352213

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Feb 2021 20:20:38

US3352213

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'OLD29'	System	24 Feb 2021 20:20:38

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '10:38'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered '24 Feb 2021 10:38'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '36.8' C	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '65'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'bpm'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'breaths/min'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '136'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'mmHg'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '83'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'mmHg'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '12:11'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered '24 Feb 2021 12:11'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '36.9' C	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '65'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'bpm'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'breaths/min'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '152'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'mmHg'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '89'	(b) (4), (b) (6)	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'mmHg'	System	24 Feb 2021 20:21:52

US3352213

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:21:59

US3352213

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:21:59

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'mRNA-1273'	System	24 Feb 2021 20:22:19
DataPoint set to visible.	System	24 Feb 2021 20:20:26

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '11:41'	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered '24 Feb 2021 11:41'	System	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'ONCE'	System	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 20:22:19

US3352213

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:23:40

US3352213

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:33
User entered 'I'	System	24 Feb 2021 20:23:40

US3352213

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 18:07:10

US3352213

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 18:07:10

US3352213

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Mar 2021 18:07:10

US3352213

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 18:07:10

US3352213

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 18:07:04

US3352213

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:25:12
User entered 'I'	System	03 Mar 2021 18:07:04

US3352213

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:54

US3352213

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 09:36:06
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Date is correct. Protocol Deviation to be filed' (Site from System).	(b) (4), (b) (6)	20 Mar 2021 14:17:42
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	18 Mar 2021 16:41:54
User entered '18 Mar 2021'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:54

US3352213

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	18 Mar 2021 16:41:54

US3352213

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered 'OLD57'	System	18 Mar 2021 16:41:54

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '18 Mar 2021'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:15'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered '18 Mar 2021 11:15'	System	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '36.8' C	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '73'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered 'bpm'	System	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '12'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered 'breaths/min'	System	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '145'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered 'mmHg'	System	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '89'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered 'mmHg'	System	18 Mar 2021 16:42:27

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30

US3352213

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30

US3352213

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'No (N)'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:30

US3352213

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered empty.	Matthew Muniz (b) (4)	18 Mar 2021 16:42:30

US3352213

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:41

US3352213

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '18 Mar 2021'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:41

US3352213

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11:31'	Matthew Muniz (b) (4)	18 Mar 2021 16:42:41

US3352213

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:40:30
User entered '18 Mar 2021 11:31'	System	18 Mar 2021 16:42:41

US3352213

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:11:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:43:57
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:09:39

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:13
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:45:24
User entered	System	16 Feb 2021 17:26:07
'USA-US066-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	16 Feb 2021 17:26:07

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:15
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Feb 2021 18:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Feb 2021 18:46:42
Data point term sent to Coder	System	13 Feb 2021 18:45:38
User entered 'Cerebrovascular Accident'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:17
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:19
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:21
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:23
User entered '29 Jan 2021'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:25
User entered empty.	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:26
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:28
User entered '03 Feb 2021'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:30
User entered empty.	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:32
User entered 'Grade 4 (Grade 4)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:33
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:35
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:37
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:40
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).		19 Feb 2021 14:23:01
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		19 Feb 2021 14:23:01
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	13 Feb 2021 18:45:52
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:42
User entered '29 Jan 2021'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:44
User entered '03 Feb 2021'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:46
User entered 'No (N)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	19 Feb 2021 14:23:01
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	13 Feb 2021 18:45:52
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		13 Feb 2021 18:45:52
User entered empty; reason for change Data Entry Error	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:52
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	13 Feb 2021 18:45:32
User entered 'Unknown (UNK)'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:48
User entered empty.	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:49
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:51
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:53
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:55
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:56
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:46:59
User entered 'Dose Delayed (DOSE DELAYED)'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:45:29
DataPoint Un-verified.	Matthew Muniz (b) (4)	03 Mar 2021 19:59:15
User entered '0' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Mar 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:03
User entered '1'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:45:24
User closed query 'Per medical record, Potassium Chloride start date 01-Feb-21 and Lovenox start date of 31Jan21 were given for this. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:45:18
Query 'Per medical record, Potassium Chloride start date 01-Feb-21 and Lovenox start date of 31Jan21 were given for this. ' answered with 'UPDATED' (Site from CRA).	Matthew Muniz (b) (4)	03 Mar 2021 19:59:21
DataPoint Un-verified.	Matthew Muniz (b) (4)	03 Mar 2021 19:59:15
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Mar 2021 19:59:15
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:50:36
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:38:18
User opened query 'Per medical record, Potassium Chloride start date 01-Feb-21 and Lovenox start date of 31Jan21 were given for this. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 20:37:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:04
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'Data confirmed.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Surisaday Mederos (b) (4) (b) (4) Surisaday Mederos (b) (4) (b) (4)	20 Apr 2021 04:00:37 19 Apr 2021 20:13:32 19 Apr 2021 20:13:20 19 Apr 2021 20:13:20
User entered '0' reason for change: Per Query Resolution	Surisaday Mederos (b) (4) (b) (4)	19 Apr 2021 20:13:20
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 06:32:44 10 Mar 2021 19:16:30
User closed query 'Please also check this, subject had procedures done per medical record that are listed in Concomitant Procedures. ' (Site from CRA). Query 'Please also check this, subject had procedures done per medical record that are listed in Concomitant Procedures. ' answered with 'Updated.' (Site from CRA). DataPoint Un-verified.		10 Mar 2021 19:16:27 10 Mar 2021 17:20:11 10 Mar 2021 17:20:03
User entered '1' reason for change: Per Query Resolution		10 Mar 2021 17:20:03
User opened query 'Please also check this, subject had procedures done per medical record that are listed in Concomitant Procedures. ' (Site from CRA).		10 Mar 2021 15:48:07

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:06
User entered '0'	Rosaidaliz Carreira (b) (4)	13 Feb 2021 18:45:32
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:07
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:09
User entered 'Dysarthria Hemipatesis'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per previous query response, pneumonia should be added as additional event. Please add.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:36:00
Query 'PV Query: Per previous query response, pneumonia should be added as additional event. Please add.' answered with 'Error, pneumonia was not a medical diagnosis. Antibiotic was taken for wound of right leg. ' (Site from Safety).	Surisaday Mederos (b) (4)	29 Apr 2021 18:15:36
User opened query 'PV Query: Per previous query response, pneumonia should be added as additional event. Please add.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 11:46:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'PV Query: Per medical records, subject was given antibiotics for pneumonia. Please consider whether this should be additional event.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:48:22
User closed query 'Per DM CLR: Narrative = CURRENTLY DOING THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 04:00:51
Query 'PV Query: Per medical records, subject was given antibiotics for pneumonia. Please consider whether this should be additional event.' answered with 'Yes, Sources will be updated. ' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 20:17:47
Query 'Per DM CLR: Narrative = CURRENTLY DOING THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Will be updated. ' (Site from DM).	Surisaday Mederos (b) (4)	19 Apr 2021 20:14:15
User opened query 'PV Query: Per medical records, subject was given antibiotics for pneumonia. Please consider whether this should be additional event.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 02:53:06
User closed query 'PV Query: As study drug was restarted, please consider updating rechallenge (did event reappear or worsen after restarting study drug?) from not applicable to yes or no. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:04:25

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:04:21
User opened query 'Per DM CLR: Narrative = CURRENTY DOING THERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:32:52
Query 'PV Query: As study drug was restarted, please consider updating rechallenge (did event reappear or worsen after restarting study drug?) from not applicable to yes or no. ' answered with 'confirmed that the event was not related to study vaccine.' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	22 Mar 2021 15:45:30
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'it was sent on February 25, 2021 10:30 AM.	Sara Gomez (b) (4) (b) (4)	22 Mar 2021 15:32:45
It was forwarded again today.' (Site from Safety).		
User opened query 'PV Query: As study drug was restarted, please consider updating rechallenge (did event reappear or worsen after restarting study drug?) from not applicable to yes or no. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 23:07:39
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:23:11

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:08:04
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:07:53
User closed query 'PV Query: Did the subject have any risk factors at the time of hospitalization, ie LDL BP, FBG, etc.? What was the extent of the evaluation?' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:07:47
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'SARS AG TEST PERFORMED 1/29/21 NEGATIVE' (Site from Safety).	Matthew Muniz (b) (4)	03 Mar 2021 19:58:58
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'submitted' (Site from Safety).	Matthew Muniz (b) (4)	03 Mar 2021 19:56:07
Query 'PV Query: Did the subject have any risk factors at the time of hospitalization, ie LDL BP, FBG, etc.? What was the extent of the evaluation?' answered with 'risk factors of hypertension, hyperlipidemia, atrial fibrillation ' (Site from Safety).	Matthew Muniz (b) (4)	03 Mar 2021 19:56:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:38:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

1866 of 2442

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:38:02
User opened query 'PV Query: Did the subject have any risk factors at the time of hospitalization, ie LDL BP, FBG, etc.? What was the extent of the evaluation?' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:37:48
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:47:11
User entered 'Subject reported that he had a stroke on January 29th and was discharged 03FEB2021. Subject is currently presenting speech difficulties and weakness to his right side. Considering serious event unclear history provided he will no be able to receive his second dose today. Currenty doing therapy.'	Rosaidaliz Carreira (b) (4) (b) (4)	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Feb 2021 18:45:32

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:35:49
Data point term sent to Coder	System	19 Feb 2021 14:35:09
User entered 'Anemia'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '29 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'None (NONE)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '1'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Subject had a cerebrovascular accident; anemia was a finding from the laboratories that were done. Acording to medical records no treament was provided.'	Surisaday Mederos (b) (4)	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 14:34:09

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 14:45:48
Data point term sent to Coder	System	19 Feb 2021 14:45:13
User entered 'Worsening of Hypertension'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '29 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User entered empty.	System	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User entered empty.	System	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'None (NONE)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'I'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User entered '0'	System	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31
User entered 'I'	System	19 Feb 2021 14:44:16

US3352213

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:31

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Foot injury - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:13:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:13:57
Data point term sent to Coder	System	19 Feb 2021 14:55:31
User entered 'Wound of right foot'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '30 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:07:05
User entered '31 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 07:24:20
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Subject was in the hospital but this was not the admission diagnosis.' (Site from System).	Surisaday Mederos (b) (4)	19 Feb 2021 14:56:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Feb 2021 14:54:34
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you! ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:37:12
Query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you! ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:21:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:21:12
User opened query 'Per CDM: "Action taken with investigational product" is recorded as 'None', however if Adverse Event started after IP then it expected to be as "Not applicable" instead of "None". Thank you! ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:08:58
User entered 'None (NONE)'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	03 Mar 2021 20:12:26
User entered '0' reason for change: New Information	(b) (4), (b) (6)	03 Mar 2021 20:12:26
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	03 Mar 2021 20:12:11
User entered '1'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per medical record, Cefepime-Start date 02-Feb-21, Gentamicin Topical-Start date 02-Feb-21, Santyl Start date 30-Jan-21, and Rocephin-01-Feb-21 were given for wound of right foot. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:58:02
Query 'Per medical record, Cefepime-Start date 02-Feb-21, Gentamicin Topical-Start date 02-Feb-21, Santyl Start date 30-Jan-21, and Rocephin-01-Feb-21 were given for wound of right foot. ' answered with 'Confirm' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 20:12:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 20:12:11
User opened query 'Per medical record, Cefepime-Start date 02-Feb-21, Gentamicin Topical-Start date 02-Feb-21, Santyl Start date 30-Jan-21, and Rocephin-01-Feb-21 were given for wound of right foot. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 20:34:02
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34
	(b) (4)	

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Pending medical records from the hospital to document treatment given.'	Surisaday Mederos (b) (4)	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 14:54:34

US3352213

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 14:54:34

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:11:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:33:59
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'subject entered information by accident ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:12:43
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:54:10
User closed query 'Per medical record subject is taking oxybutynin, rosuvastatin, and tamsulosin. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:54:04
Query 'Per medical record subject is taking oxybutynin, rosuvastatin, and tamsulosin. ' answered with 'Medications have been added.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:36:47

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:11:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per medical record subject is taking oxybutynin, rosuvastatin, and tamsulosin. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:10:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:50:32

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 20:53:16
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 Aug 2020 20:53:16
Data point term sent to Coder	System	22 Aug 2020 20:51:52
User entered 'hydrochlorothiazide'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'hypertension'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:07:44
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	08 Oct 2020 19:27:31
User entered '12.5' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Oct 2020 19:27:23
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:21:11
User entered '10'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'un UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 20:51:26

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 20:53:16
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 Aug 2020 20:53:16
Data point term sent to Coder	System	22 Aug 2020 20:52:54
User entered 'metoprolol'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'hypertension'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '100'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'un UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 20:52:08

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
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: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 20:53:16
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 Aug 2020 20:53:16
Data point term sent to Coder	System	22 Aug 2020 20:52:53
User entered 'nifedipine'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'hypertension'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '60'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'un UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 20:52:50

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 15:50:54
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:50:17
User closed query 'Please correct spelling to ELIQUIS. Also provide source for this ConMed and for Atorvastatin, Clonidine, and Aspirin. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:50:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:24:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:24:07
Data point term sent to Coder	System	05 Mar 2021 17:23:07
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 17:22:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:44:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:44:53
Data point term sent to Coder	System	05 Mar 2021 15:43:46
Query 'Please correct spelling to ELIQUIS. Also provide source for this ConMed and for Atorvastatin, Clonidine, and Aspirin. ' answered with 'DATA UPDATED' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 15:43:39
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 15:43:22
User entered 'ELIQUIS' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:43:22

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Please correct spelling to ELIQUIS. Also provide source for this ConMed and for Atorvastatin, Clonidine, and Aspirin. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:56:15
Query 'Please correct spelling to ELIQUIS. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:55:15
User opened query 'Please correct spelling to ELIQUIS. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:51:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:48:51
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 Feb 2021 17:48:51
Data point term sent to Coder	System	19 Feb 2021 14:09:48
User entered 'ELEQUIS'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 15:51:12
DataPoint Verified.		10 Mar 2021 15:51:09
DataPoint Un-verified.		10 Mar 2021 15:51:05
DataPoint Verified.		10 Mar 2021 15:50:10
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication (MH#7 has a stop date of Jan 2016). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication (MH#7 has a stop date of Jan 2016). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'MH updated to match CC Med' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:26:26
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication (MH#7 has a stop date of Jan 2016). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 15:47:44
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 10:08:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:51:14
User closed query 'This should have a different indication since Cerebrovascular Accident has an end date of 03-Feb-2021, is this being taken for Atrial Fibrillation? Per medical record subject is on anticoagulant for Atrial Fibrillation. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:50:08
User closed query 'Per DM CLR: Please review AE eCRF's AE #1 CEREBROVASCULAR ACCIDENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:49:57
	(b) (4), (b) (6)	08 Mar 2021 07:25:22

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review AE eCRF's AE #1 CEREBROVASCULAR ACCIDENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:23:15
Query 'This should have a different indication since Cerebrovascular Accident has an end date of 03-Feb-2021, is this being taken for Atrial Fibrillation? Per medical record subject is on anticoagulant for Atrial Fibrillation. Please clarify. ' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:22:10
User entered 'Atrial fibrillation' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 17:22:01
User opened query 'Per DM CLR: Please review AE eCRF's AE #1 CEREBROVASCULAR ACCIDENT (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:41:41
User opened query 'This should have a different indication since Cerebrovascular Accident has an end date of 03-Feb-2021, is this being taken for Atrial Fibrillation? Per medical record subject is on anticoagulant for Atrial Fibrillation. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:01:42
Query 'This should have a different indication since Cerebrovascular Accident has an end date of 03-Feb-2021, is this being taken as a Cardiac Prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:58:31
User opened query 'This should have a different indication since Cerebrovascular Accident has an end date of 03-Feb-2021, is this being taken as a Cardiac Prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 18:50:10
User entered 'Cerebrovascular accident'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 15:51:18
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:50:29
User entered '5'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 15:51:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:50:37
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'twice daily (BID)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 14:09:36

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 14:12:48
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 Feb 2021 14:12:48
Data point term sent to Coder	System	19 Feb 2021 14:11:51
User entered 'Atorvastatin'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Hyperlipidemia'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '80'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 14:11:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 14:14:48
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 Feb 2021 14:14:48
Data point term sent to Coder	System	19 Feb 2021 14:13:57
User entered 'Clonidine'	Surisaday Mederos (b) (4) (b) (4)	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Hypertension'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0.1'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'twice daily (BID)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 14:13:20

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
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 Feb 2021 14:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 14:22:48
Data point term sent to Coder	System	19 Feb 2021 14:21:59
User entered 'Aspirin'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Cardiovascular Prophylaxis'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '81'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:21:48
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 14:21:48

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:38:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:38:53
Data point term sent to Coder Coding entries removed.	System Matthew Muniz (b) (4)	03 Mar 2021 20:45:22 03 Mar 2021 20:45:12
User entered 'GENTAMICIN TOPICAL 0.01%' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Mar 2021 20:45:12
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 11:20:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 11:20:53
Data point term sent to Coder User entered 'Gentamicin Topical'	System Surisaday Mederos (b) (4) (b) (4)	22 Feb 2021 19:55:37 22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Wound of right foot'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Note, 0.1% is a drug strength, please update medication name to include this drug strength and update dose and dose unit with the actual dose administered (eg, Medication Name: GENTAMICIN 0.1%; Dose=1; Dose Unit=Application). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:39:13
Query 'Per DM CLR: Note, 0.1% is a drug strength, please update medication name to include this drug strength and update dose and dose unit with the actual dose administered (eg, Medication Name: GENTAMICIN 0.1%; Dose=1; Dose Unit=Application). Update as appropriate.' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	03 Mar 2021 20:45:17
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Mar 2021 20:45:12
User opened query 'Per DM CLR: Note, 0.1% is a drug strength, please update medication name to include this drug strength and update dose and dose unit with the actual dose administered (eg, Medication Name: GENTAMICIN 0.1%; Dose=1; Dose Unit=Application). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:42:04
User entered '0.1'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Other (OTHER)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'APPLICATION' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Mar 2021 20:45:12
User entered '0.01 % one application'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'as needed (PRN)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Topical (TOPICAL)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2 Feb 2021'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User entered empty.	System	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User entered empty.	System	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:22
User entered empty.	System	22 Feb 2021 19:55:03

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 14:14:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 14:14:59
Data point term sent to Coder	System	23 Feb 2021 14:13:54
User entered 'Cefepime'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Wound of right foot'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'g (g)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'as needed (PRN)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User entered empty.	System	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User entered empty.	System	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:26
User entered empty.	System	23 Feb 2021 14:13:06

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:40:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:40:07
Data point term sent to Coder	System	23 Feb 2021 14:18:09
User entered 'Hydralazine'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Worsening of Hypertension'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '25'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'as needed (PRN)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '31 Jan 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User entered empty.	System	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User entered empty.	System	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:30
User entered empty.	System	23 Feb 2021 14:17:18

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:40:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:40:08
Data point term sent to Coder	System	23 Feb 2021 14:28:24
User entered 'Hydralazine'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Worsening of hypertension.'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '50'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User entered empty.	System	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User entered empty.	System	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:38
User entered empty.	System	23 Feb 2021 14:27:53

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:40:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:40:41
Data point term sent to Coder	System	23 Feb 2021 14:37:36
User entered 'Rocephin'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Wound of Right foot'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'g (g)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '1 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '1 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User entered empty.	System	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User entered empty.	System	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:41
User entered empty.	System	23 Feb 2021 14:37:07

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:38
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: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:27:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:27:08
Data point term sent to Coder	System	23 Feb 2021 14:41:39
User entered 'Potassium Chloride'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Worsening of hypertension'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:56:21
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	19 Mar 2021 18:39:03
User entered '500' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Mar 2021 18:38:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:17:15
User entered '100'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '1 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '1 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User entered empty.	System	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User entered empty.	System	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:43
User entered empty.	System	23 Feb 2021 14:41:27

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: DERMATOLOGICALS, ATC: PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS, ATC: ENZYMES, ATC: PROTEOLYTIC ENZYMES, PRODUCT: COLLAGENASE, PRODUCTSYNONYM: SANTYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 14:45:02
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 Feb 2021 14:45:02
Data point term sent to Coder	System	23 Feb 2021 14:44:41
User entered 'Santyl'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Wound of right foot'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:28:20
Query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:48:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:48:28
User opened query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:40:56
User entered 'one'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Other (OTHER)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'APPLICATION.' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 15:48:36
User entered 'One application.'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'as needed (PRN)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Topical (TOPICAL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Con Med start date (30 JAN 2021) is prior to the start date of the corresponding AE (31 JAN 2021). Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:27:11
Query 'Per DM CLR: Con Med start date (30 JAN 2021) is prior to the start date of the corresponding AE (31 JAN 2021). Please review and reconcile the Con Med and AE start dates as appropriate. ' answered with 'data updated to match AE' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 16:07:33
User opened query 'Per DM CLR: Con Med start date (30 JAN 2021) is prior to the start date of the corresponding AE (31 JAN 2021). Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:14:00
User entered '30 Jan 2021'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '3 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:48
User entered empty.	System	23 Feb 2021 14:44:14

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 22:34:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 22:34:54
Data point term sent to Coder	System	23 Feb 2021 14:49:43
User entered 'Lovenox'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:56:42
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	19 Mar 2021 18:31:23
DataPoint Un-verified.	Matthew Muniz (b) (4)	19 Mar 2021 18:31:16
User entered 'No (N)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Mar 2021 18:31:16
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 1). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:19:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:30
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:26
User entered 'Cerebrovascular Accient'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:19
User entered '100'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:17
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:13
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:10
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:06
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:53:00
User entered 'Subcutaneous (SUBCUTANEOUS)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:54
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:51
User entered '31 Jan 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:46
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:44
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:41
User entered '2 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:52:33
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User entered '1'	System	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User entered '1'	System	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:50
User entered '804 (804)'	System	23 Feb 2021 14:48:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 14:52:05
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 Feb 2021 14:52:05
Data point term sent to Coder	System	23 Feb 2021 14:51:46
User entered 'Tamsulosin'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	23 Feb 2021 14:51:46
User entered 'Benigh Prostatic Hyperplasia'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0.4'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '30 Jan 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User entered '1'	System	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User entered '1'	System	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:52
User entered '804 (804)'	System	23 Feb 2021 14:50:54

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:29:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 17:29:56
Data point term sent to Coder	System	05 Mar 2021 17:29:24
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 17:28:58
User entered 'Rosuvastatin (crestor)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 17:28:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 14:59:01
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 Feb 2021 14:59:01
Data point term sent to Coder	System	23 Feb 2021 14:58:06
User entered 'Crestor'	Surisaday Mederos (b) (4) (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Hyperlipidemia'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '20'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '29 Jan 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '2 Feb 2021'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57
	(b) (4)	

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered '1'	System	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered '1'	System	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:56
User entered '804 (804)'	System	23 Feb 2021 14:57:57

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 17:37:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 17:37:55
Data point term sent to Coder	System	05 Mar 2021 17:36:36
User entered 'oxybutynin'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:27:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH updated to match Con Med' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 16:25:33
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:17:28
User entered 'Urinary frequency'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '5'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'un Feb 2020'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 17:36:28

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:11:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:39
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User closed query 'Per medical record subject had another CT of Brian w/o contrast on 01-Feb-2021, please add. ' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:42:50
Query 'Per medical record subject had another CT of Brian w/o contrast on 01-Feb-2021, please add. ' answered with 'Procedure has been added.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:40:44
User opened query 'Per medical record subject had another CT of Brian w/o contrast on 01-Feb-2021, please add. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:15:31
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:14:44
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:58:18
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:19
User entered '29 Jan 2021' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	19 Feb 2021 14:59:23
User entered '30 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 14:58:53

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:20
User entered 'X RAY CHEST'	Surisaday Mederos (b) (4)	19 Feb 2021 14:58:53
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:22
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	19 Feb 2021 14:58:53
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:25
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 14:58:53
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:39
User entered '29 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:17
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:40
User entered 'CT OF THE BRAIN WITHOUT CONTRAST.'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:17

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:43
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:17
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:44
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:17
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered '29 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:56
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'ECG'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:56

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:56
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:44
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 15:00:56
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered '30 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 15:01:44
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'MRI BRAIN WITHOUT CONTRAST'	Surisaday Mederos (b) (4)	19 Feb 2021 15:01:44
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	19 Feb 2021 15:01:44
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 15:01:44
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered '30 Jan 2021'	Surisaday Mederos (b) (4)	19 Feb 2021 15:02:21
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'X RAY ANKLE COMPLETE RIGHT'	Surisaday Mederos (b) (4)	19 Feb 2021 15:02:21

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	19 Feb 2021 15:02:21

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:48
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:53
User entered empty.	Surisaday Mederos (b) (4)	19 Feb 2021 15:02:21
	(b) (4)	

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:42:40
User entered '01 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 17:40:17

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:42:40
User entered 'CT scan of the brain without contrast'	(b) (4), (b) (6)	05 Mar 2021 17:40:17

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:42:40
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	05 Mar 2021 17:40:17

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:51
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 15:42:40
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 17:40:17

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '13 Feb 2021'	Surisaday Mederos (b) (4)	22 Apr 2021 17:29:00

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Occupational Therapy'	Surisaday Mederos (b) (4)	22 Apr 2021 17:29:00

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	22 Apr 2021 17:29:00

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	22 Apr 2021 17:29:00

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:11:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:55
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered '13 Feb 2021'	Surisaday Mederos (b) (4)	22 Apr 2021 17:30:11

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:11:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:55
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Speech Therapy'	Surisaday Mederos (b) (4)	22 Apr 2021 17:30:11

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:11:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:55
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	22 Apr 2021 17:30:11

US3352213

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:11:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:36:55
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:16:23
User entered empty.	Surisaday Mederos (b) (4)	22 Apr 2021 17:30:11
	(b) (4)	

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '16/Feb/2021 11:26'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:19

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.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.		19 Feb 2021 16:46:14
Reviewed for Safety.		19 Feb 2021 16:46:10
User entered 'I'		16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '19/Feb/2021 11:46'	System	19 Feb 2021 16:46:43

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:19

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.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 17:09:27
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 16:46:43

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '04/Mar/2021 12:09'	System	04 Mar 2021 17:09:51

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:19

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.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:49:16
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 17:09:51

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '11/Mar/2021 12:50'	System	11 Mar 2021 17:50:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:19

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.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 15:49:16
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 17:50:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'USA-US066-2021-MRNA-1273-P301000006'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Yes (Y)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'No (N)'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Howard'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'schwartz'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '7265 SHeridan Street SUite 210'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'Pembroke Pines'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered 'FL'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:26:21
User entered '33024'	System	16 Feb 2021 17:26:07

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:18
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 16:46:10
User entered 'US'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 15:49:47
User entered '4'	System	11 Mar 2021 17:50:30
User entered '3'	System	04 Mar 2021 17:09:51
User entered '2'	System	19 Feb 2021 16:46:43
User entered '1'	System	16 Feb 2021 17:26:30

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered '20/Apr/2021 11:49'	System	20 Apr 2021 15:49:47

US3352213

Folder: SAE USA-US066-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:19

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.	Howard schwartz (b) (4)	28 Apr 2021 13:17:50
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 15:49:47