

US3232050 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:04:42

All time stamps listed in this document are displayed in GMT

US3232050

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 13:38:55

Generated On: 09 Jun 2021 16:04:42

[Participant ID](#)

US3232050

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

US3232050

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3232050

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3232050

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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

US3232050

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3232050

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Were any significant conditions reported?

Yes ☒

No ☐

US3232050

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	DIABETES (TYPE II)
Start date (dd MMM yyyy)	20 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)	_____

US3232050

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	DENTURES
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3232050

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	LASER VISION CORRECTION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3232050

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	HYPERTENSION
Start date (dd MMM yyyy)	16 APR 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)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232050

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	20 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)	_____

US3232050

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	10 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3232050

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	LEFT ELBOW TENDONITIS
Start date (dd MMM yyyy)	15 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232050

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	MIXED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	30 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232050

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	02 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)	

US3232050

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	05 JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232050

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	FATTY LIVER
Start date (dd MMM yyyy)	23 MAR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232050

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	CHRONIC ANEMIA
Start date (dd MMM yyyy)	23 MAY 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)	MAY 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3232050

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	CIRRHOSIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3232050

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	PORTAL HYPERTENSIVE GASTROPATHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3232050

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

Condition	COLONOSCOPY SECONDARY DIVERTICULOSIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3232050

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:05
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	99.6 kg
BMI (<i>xxx.x</i>)	32.89734 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232050

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3232050

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OUTDOOR SERVICE PROVIDER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3232050

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186212

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 ☒

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Height	ND - Not Done
Weight	ND - Not Done

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:52 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:52
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3232050

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 AUG 2020

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:05

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

US3232050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

11:43 (24 HR)

Collection date and time (derived)

14 AUG 2020 11:43

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Collection date (<i>dd MMM yyyy</i>)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	14 AUG 2020 11:10
Nasopharyngeal Swab 2	No		

US3232050

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 12:31

PC Open Date & Time

14 AUG 2020 12:25

PC Close Date & Time

14 AUG 2020 14:55

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.6 °F

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

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

PC Time Stamp	15 AUG 2020 07:16
PC Open Date & Time	14 AUG 2020 15:50
PC Close Date & Time	15 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 09:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 AUG 2020 15:52

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:21

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 15:25

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

19 AUG 2020 15:41

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 08:55

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:32

PC Open Date & Time

14 AUG 2020 12:25

PC Close Date & Time

14 AUG 2020 14:55

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 07:19

PC Open Date & Time

14 AUG 2020 15:50

PC Close Date & Time

15 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 09:19

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 15:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:22

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 15:25

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 15:41

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 08:53

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 12:32
PC Open Date & Time	14 AUG 2020 12:25
PC Close Date & Time	14 AUG 2020 14:55

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 07:20
PC Open Date & Time	14 AUG 2020 15:50
PC Close Date & Time	15 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2862

EAB) (1725)

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 09:20
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

58 of 2862

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 15:54
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2862

EAB) (1725)

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:22
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2862

EAB) (1725)

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 15:26
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

64 of 2862

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:42
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

66 of 2862

EAB) (1725)

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 08:56
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3232050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:04
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

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)	11 SEP 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:14
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3232050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 10:58

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

US3232050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

10:05 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:05

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	11 SEP 2020 10:05
Nasopharyngeal Swab 2	No		

US3232050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 11:18

PC Close Date & Time

11 SEP 2020 13:48

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 14:43

PC Close Date & Time

12 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 11:18

PC Close Date & Time

11 SEP 2020 13:48

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 14:43

PC Close Date & Time

12 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

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

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 11:18

PC Close Date & Time

11 SEP 2020 13:48

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 14:43

PC Close Date & Time

12 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

102 of 2862

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

106 of 2862

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

108 of 2862

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

110 of 2862

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 2862

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:37:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:36

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 10:10
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3232050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:17 (24 HR)
Collection date and time (derived)	9 OCT 2020 10:17

US3232050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:41:37

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

18 OCT 2020 10:33:00

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 11:14:49

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 19:24:42

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 08:14:07
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 17:44:34

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 09:11:26

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 15:13:54
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 17:02:03

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 21:11:46

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 08:34:26

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 09:27:07

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

17 JAN 2021 12:07:06

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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	24 JAN 2021 15:40:13
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

01 FEB 2021 17:46:16

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

07 FEB 2021 19:11:32

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

15 FEB 2021 09:00:14

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 07:34:11

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

28 FEB 2021 08:56:21

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 MAR 2021 09:09:32
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 MAR 2021 10:16:07
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

21 MAR 2021 07:59:24

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

30 MAR 2021 12:59:21

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 18:04:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

13 APR 2021 12:08:27

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 12:00:52

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 08:11:34

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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°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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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°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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	09 DEC 2021 23:59
---	-------------------

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 <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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	18 AUG 2022 23:59
---	-------------------

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	06 OCT 2022 23:59
---	-------------------

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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°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 ☐

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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="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"/>

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3232050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:04:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 08:56:39

US3232050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:36:32

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:36:32

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:40:08

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:40:08

Generated On: 09 Jun 2021 16:04:42

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3232050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:40:08

Generated On: 09 Jun 2021 16:04:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3232050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 MAR 2021
Collection time (<i>00:00-23:59</i>)	12:03 (24 HR)
Collection date and time (derived)	19 MAR 2021 12:03

US3232050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 16:00:08

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 16:00:08

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232050

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

If Contact Not Made, please provide Comments

US3232050

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3232050

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:04:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3232050

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

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

Visit date (dd MMM yyyy)	21 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
------------	---------------

US3232050

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Date of updated informed consent (*dd MMM yyyy*) 21 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3232050

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:40:07

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	13:06 (24 HR)
Collection date and time (derived)	21 JAN 2021 13:06

US3232050

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 13:38:56

Generated On: 09 Jun 2021 16:04:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	12:52
Collection Date and Time (derived)	21 JAN 2021 12:52

US3232050

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:52:57

Generated On: 09 Jun 2021 16:04:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	23 SEP 2020
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)	24 SEP 2020
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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID

Adverse event

WORSENING SEVERE ACUTE
CHRONIC SYMPTOMATIC
ANEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

336 of 2862

EAB) (1725)

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED.

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

Admitted to ICU Derived (CSA Programming Field Only)	0
--	---

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	
Adverse event	ULCER OF DUODENUM
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)	4 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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	True
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	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED.

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	USA-US105-2021-MRNA-1273-P30 1000007
Adverse event	HYPOTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	06 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003

346 of 2862

EAB) (1725)

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID

Adverse event

WORSENING PORTAL
HYPERTENSIVE GASTROPATHY

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)

05 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

348 of 2862

EAB) (1725)

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	CHRONIC CONDITION
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

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID

Adverse event

WORSENING HEPATIC
CIRRHOSIS

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)

05 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

350 of 2862

EAB) (1725)

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID

Adverse event

ESOPHAGEAL VARICES

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)

05 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

352 of 2862

EAB) (1725)

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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	True
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	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	
Adverse event	GASTRITIS
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)	05 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

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	True
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	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	USA-US105-2021-MRNA-1273-P30 1000007
Adverse event	GASTROINTESTINAL BLEED
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	06 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

73 Y/O MALE W/HX OF
HYPERTENSION,
HYPERLIPIDEMIA,
OBSTRUCTIVE SLEEP APNEA,
BENIGN PROSTATIC
HYPERTROPHY, TYPE 2
DIABETES MELLITUS HAD AN
EPISODE OF DIZZINESS, NOT
FEELING WELL SOME BLURRY
VISION, AND SHORTNESS OF
BREATH. HIS BLOOD PRESSURE
WAS LOW AND HE WAS
TRANSFERRED TO ED. HE
REPORTED BLACK STOOL PAST
COUPLE OF DAY. ALSO 2
EPISODES OF HEMATEMESIS
SINCE LAST 2 DAYS. HE DID
NOT SEEK MEDICAL
ATTENTION THEN UNTIL
TODAY HE HAD A
COLONOSCOPY IN 2018 WHICH
SHOWS FINDING OF
DIVERTICULOSIS. HE
PRESENTED TO ED FOR
PERSISTENT MELENA AND
SYMPTOMS OF WEAKNESS. HE
WAS FOUND TO HAVE
HYPOTENSION AND ANEMIA
WITH HEMOGLOBIN OF 6.9.
AFTER TREATMENT OF 3 UNITS
OF PRBC AND IV FLUIDS HIS
BLOOD PRESSURE AND
HEMOGLOBIN IMPROVED.
INITIAL VITALS: 74/34
IMPROVED TO 120/60. INITIAL
HEMOGLOBIN 6.9 IMPROVED
TO 9.9, LACTIC ACID OF 3.6.
HOSPITALIZED FROM ED WITH
SEVERE ACUTE ON CHRONIC
SYMPTOMATIC ANEMIA DUE
TO GI BLEED

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

AEID	
Adverse event	WORSENING MIXED HYPERLIPIDEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 17:43:09

Generated On: 09 Jun 2021 16:04:42

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 13:38:56

Generated On: 09 Jun 2021 16:04:42

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

Yes ☒

No ☐

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

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

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)

367 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 AUG 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"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROHYLACTIC

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

369 of 2862

EAB) (1725)

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 APR 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"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication SITAGLIPTINE METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 50-1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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

375 of 2862

EAB) (1725)

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 APR 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"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication SANDOSTATIN

Prophylaxis Yes ☐
No ☒

Indication UPPER GASTROINTESTINAL
BLEED

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)

377 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication UPPER GASTROINTESTINAL
BLEED/ULCER OF DUODENUM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication SANDOSTATIN

Prophylaxis Yes ☐
No ☒

Indication UPPER GASTROINTESTINAL
BLEED

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS INFUSION DAILY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication UPPER GASTROINTESTINAL
BLEED/ULCER OF DUODENUM

Dose per administration 1920

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS INFUSION DAILY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐
No ☒

Indication UPPER GASTROINTESTINAL
BLEED/WORSENING SEVERE
ACUTE CHRONIC
SYMPTOMATIC
ANEMIA/ESOPHAGEAL
VARICES

Dose per administration 3

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify STAT DAILY

Route of administration Oral ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	05 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING MIXED
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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication .9% SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOTENSION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS DAILY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN (STOMACH) SECONDARY
TO GI BLEED

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)

391 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PAIN(STOMACH) /ANESTHESIA
(EGD)

Dose per administration 20/50

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)

393 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication FLUMAZENIL

Prophylaxis Yes ☒
No ☐

Indication PREVENTIVE OF ANESTHESIA
OVERDOSE

Dose per administration .4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	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)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication ANESTHESIA (EGD)

Dose per administration 1-2

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

397 of 2862

EAB) (1725)

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input 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)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication NARCAN

Prophylaxis Yes ☒
No ☐

Indication PREVENTIVE OF ANESTHESIA
OVERDOSE

Dose per administration .4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA (GASTRITIS)

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE AS NEEDED

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA (GASTRITIS)

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

403 of 2862

EAB) (1725)

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication ESOPHAGOGASTRODUODENOS
COPY

Dose per administration 300

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)

405 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication SODIUM CHLORIDE .9% FLUSH

Prophylaxis Yes ☒
No ☐

Indication PERIPHERAL IV FLUSH
(PREVENTIVE)

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication ESOPHAGOGASTRODUODENOS
COPY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

409 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

Name of Medication HIBICLENS

Prophylaxis Yes ☐
No ☒

Indication PRE-OPERATIVE PROTOCOL
(EGD)

Dose per administration 4 %

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

If dose unit is Other, specify SOLUTION

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)

411 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 16:21:55

Generated On: 09 Jun 2021 16:04:42

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 13:38:56

Generated On: 09 Jun 2021 16:04:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 13:38:56

Generated On: 09 Jun 2021 16:04:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 MAR 2021	ESOPHAGOGASTRODUODENOSC OPY	Adverse Event	
04 MAR 2021	BLOOD TRANSFUSION (PACKED RED BLOOD CELLS)	Adverse Event	

US3232050

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:04:42

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

US3232050

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:04:42

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 ☐

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	08/MAR/2021 12:48
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/MAR/2021 10:50
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	11/MAR/2021 09:30
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	12/MAR/2021 09:01
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/MAR/2021 13:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:06
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	18/MAR/2021 11:51
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (8)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	22/MAR/2021 08:10
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (9)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/MAR/2021 11:17
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (10)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:31
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (11)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	29/MAR/2021 09:24
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

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (12)

Data signed: (b) (4) 09 Apr 2021 16:21:57

Generated On: 09 Jun 2021 16:04:42

SAEID	USA-US105-2021-MRNA-1273-P301000007
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	06/APR/2021 08:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3232050 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232050

Form: Participant Creation

Generated On: 09 Jun 2021 16:04:42

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:01:16
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered 'US3232050'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 15:54:29

US3232050

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:30
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:26:06

US3232050

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:30
User entered '14 AUG 2020'	(b) (4), (b) (6) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 15:54:30

US3232050

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:26:06

US3232050

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'SCRN'	(b) (4), (b) (6) System	14 Aug 2020 18:26:06

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered (b) (6) 1947'	(b) (4), (b) (6) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 15:54:31

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '73'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'YEARS'	(b) (4), (b) (6) System	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '73'	(b) (4), (b) (6) System	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered 'Male (M)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:04:58
	(b) (4), (b) (6)	
User entered 'I'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:27:16
	(b) (4)	

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:04:58
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:16

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered '14 Aug 2020'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Aug 2020'	(b) (4), (b) (6) System	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:05:19
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 17:20:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 17:20:32
User entered 'Amendment 2 (2)' reason for change:	Adreanna Pou (b) (4)	14 Aug 2020 17:20:32
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 17:20:27
User entered empty.	Adreanna Pou (b) (4)	14 Aug 2020 17:20:27
	(b) (4)	

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered 'Yes (Y)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered empty.	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered empty.	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered 'No (N)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:27

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:19
User entered empty.	(b) (4), (b) (6) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 15:54:30

US3232050

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '1'	(b) (4), (b) (6) System	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:04:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:05:31
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:27:38

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition TYPE II DIABETES. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Oct 2020 15:22:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:09:46
Data point term sent to Coder	System	02 Oct 2020 16:08:57
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition TYPE II DIABETES. If yes, please ensure only one entry is recorded. ' answered with 'Corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Oct 2020 16:08:19
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	02 Oct 2020 16:08:14
User entered 'DIABETES (type II)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Oct 2020 16:08:14
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition TYPE II DIABETES. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 13:53:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:29:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:29:22
Data point term sent to Coder	System	14 Aug 2020 18:28:46

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

[Condition](#)

Audit	User	Time (GMT)
User entered 'Diabetes'	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '20 Feb 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Feb 2020'	(b) (4), (b) (6) System	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 18:28:17

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Denture wearer, LLT: Denture wearer - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:34
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:41:00
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Denture wearer, LLT: Denture wearer - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:40
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:40:51
User entered 'dentures'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:40:22
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'un UNK 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:40:22
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'un UNK 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2020'	(b) (4), (b) (6) System	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2020'	(b) (4), (b) (6) System	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 15:40:22

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Vision correction operation, LLT: Vision correction operation - version MedDRA\23.0.	Coder Import	01 Feb 2021 21:41:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import	01 Feb 2021 21:41:31
Data point term sent to Coder	System	01 Feb 2021 21:41:01
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
Query 'Per DM CLR: Please specify the laterality of LASER VISION CORRECTION(left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:59:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:10:30
User opened query 'Per DM CLR: Please specify the laterality of LASER VISION CORRECTION(left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:56:31
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:55:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Vision correction operation, LLT: Vision correction operation - version MedDRA\23.0.	Coder Import	01 Sep 2020 23:42:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import	01 Sep 2020 23:42:34

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 15:43:59
User entered 'laser vision correction'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:43:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'un UNK 2015'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'un UNK 2015'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2015'	(b) (4), (b) (6) System	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2015'	(b) (4), (b) (6) System	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2015'	(b) (4), (b) (6) System	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2015'	(b) (4), (b) (6) System	24 Aug 2020 15:43:44

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:34
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:41:00
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 13:23:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 13:23:31
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 13:22:20
Coding entries removed.	Jerrica Sullivan (b) (4)	09 Nov 2020 13:22:14
	(b) (4)	
User entered 'hypertension' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Nov 2020 13:22:14
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:45:38
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:45:02
User entered 'high blood pressure'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:44:06
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '16 Apr 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Apr 2020'	(b) (4), (b) (6) System	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:44:06

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:33
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:41:01
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:45:38
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:45:04
User entered 'Type II diabetes'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:44:31
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '20 Feb 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:44:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:44:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Aug 2020 15:44:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:44:31
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:44:31
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:44:31
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Feb 2020'	(b) (4), (b) (6) System	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:44:31

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
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)	01 Feb 2021 21:41:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:33
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:41:01
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
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)	09 Nov 2020 13:27:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 13:27:37
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 13:27:23
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Jerrica Sullivan (b) (4)	09 Nov 2020 13:26:46
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '10 Aug 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Aug 2020'	(b) (4), (b) (6) System	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	09 Nov 2020 13:26:46

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendonitis - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 21:41:32
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:41:01
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:59
	(b) (4), (b) (6)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendonitis - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 13:27:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 13:27:36
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 13:26:23
Coding entries removed.	Jerrica Sullivan (b) (4)	09 Nov 2020 13:26:10
	(b) (4)	
User entered 'LEFT ELBOW TENDONITIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Nov 2020 13:26:10
	(b) (4)	
Query 'Per DM CLR: Please specify the location and/or type of TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	05 Nov 2020 21:00:08
' canceled (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please specify the location and/or type of TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	11 Sep 2020 13:57:49
' (Site from DM).	(b) (4), (b) (6)	

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendonitis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:47:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 15:47:40
Data point term sent to Coder	System	24 Aug 2020 15:46:04
User entered 'tendonitis'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:45:17
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '15 Jul 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:59
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jul 2020'	(b) (4), (b) (6) System	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 15:45:17

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:15:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:15:33
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:14:56
User entered 'Mixed hyperlipidemia'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '30 Jan 2020'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:14:44
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2020'	(b) (4), (b) (6) System	15 Mar 2021 21:14:44

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	15 Mar 2021 21:14:44

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:14:44

US3232050

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:14:44

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:15:57
User entered 'obstructive sleep apnea'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:21
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '02 Feb 2020'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:21
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:21
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:21
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:45:15
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:15:21

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:21
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Feb 2020'	(b) (4), (b) (6) System	15 Mar 2021 21:15:21

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2020'	(b) (4), (b) (6) System	15 Mar 2021 21:15:21

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:21

US3232050

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:21

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:15:57
User entered 'diverticulosis'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:35
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '05 Jan 2018'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:35
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:35
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:35
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:45:15
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:15:35

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:35
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Mar 2021 21:15:35

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2018'	(b) (4), (b) (6) System	15 Mar 2021 21:15:35

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:35

US3232050

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:35

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:16:37
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:15:57
User entered 'Fatty liver'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '23 Mar 2009'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:15:50
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Mar 2009'	(b) (4), (b) (6) System	15 Mar 2021 21:15:50

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2009'	(b) (4), (b) (6) System	15 Mar 2021 21:15:50

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:50

US3232050

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 21:15:50

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 17:44:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 17:44:49
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:44:11
User entered 'chronic anemia'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:44:08
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '23 May 2013'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:44:08
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:44:08
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 19:02:27
User entered 'Yes (Y)'	Rambod Rouhbakhsh	22 Mar 2021 17:44:08
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:44:08
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:44:08
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'May 2013'	(b) (4), (b) (6) System	22 Mar 2021 17:44:08

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2013'	(b) (4), (b) (6) System	22 Mar 2021 17:44:08

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:44:08

US3232050

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:44:08

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis liver - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 18:08:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 18:08:04
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:51:38
User entered 'cirrhosis'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:40
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:40

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:40

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:40

US3232050

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:40

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages	Coder Import (b) (4)	22 Mar 2021 17:52:49
NEC, HLT: Gastric and oesophageal haemorrhages,	(b) (4)	
PT: Portal hypertensive gastropathy, LLT: Portal hypertensive gastropathy - version MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Mar 2021 17:52:49
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:51:38
User entered 'portal hypertensive gastropathy'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:59
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:59
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:59
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 19:02:27
User entered 'Yes (Y)'	Rambod Rouhbakhsh	22 Mar 2021 17:50:59
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:59
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:50:59
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:59

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:59

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:59

US3232050

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	22 Mar 2021 17:50:59

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	Rambod Rouhbakhsh	06 Apr 2021 08:20:20
User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	(b) (4)	05 Apr 2021 19:08:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Apr 2021 19:08:26
Data point term sent to Coder	(b) (4)	05 Apr 2021 15:55:45
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	System	05 Apr 2021 15:55:05
Coding entries removed.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:55:00
Signature has been broken.	(b) (4)	05 Apr 2021 15:55:00
User entered 'COLONOSCOPY secondary diverticulosis' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 15:55:00
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4)	02 Apr 2021 10:23:46
User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 19:02:27
User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Rambod Rouhbakhsh	22 Mar 2021 17:55:57
	(b) (4)	
	Coder Import (b) (4)	
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Mar 2021 17:55:57
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 17:54:44
User entered 'colonoscopy'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'un UNK 2018'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:00:32
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	29 Mar 2021 13:01:41
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	29 Mar 2021 13:01:27
	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 04:50:40
	(b) (4), (b) (6)	
	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered 'un UNK 2018' reason for change:	Jerrica Sullivan (b) (4)	29 Mar 2021 13:01:27
Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:45:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:02:27
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	22 Mar 2021 17:53:53
	(b) (4)	

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'Jan 2018'	(b) (4), (b) (6) System	22 Mar 2021 17:53:53

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '2018'	(b) (4), (b) (6) System	22 Mar 2021 17:53:53

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User entered 'Jan 2018'	System	29 Mar 2021 13:01:27
User entered empty.	System	22 Mar 2021 17:53:53

US3232050

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User entered '2018'	System	29 Mar 2021 13:01:27
User entered empty.	System	22 Mar 2021 17:53:53

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '14 Aug 2020'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:14
	(b) (4), (b) (6)	
User entered '11:05'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:29:36
	(b) (4)	

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '14 Aug 2020 11:05'	(b) (4), (b) (6) System	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:14
	(b) (4), (b) (6)	
User entered '174' cm	Jerrica Sullivan (b) (4)	14 Aug 2020 18:29:36
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:14
	(b) (4), (b) (6)	
User entered '99.6' kg	Jerrica Sullivan (b) (4)	14 Aug 2020 18:29:36
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
Amendment Manager: User entered '32.89734'	System	16 Sep 2020 23:57:16
User entered '32.9'	System	14 Aug 2020 18:29:36
DataPoint set to visible.	System	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	14 Aug 2020 18:29:36
DataPoint set to visible.	System	14 Aug 2020 17:20:48

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '98.0' F	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered 'Oral (Oral)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '82'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '17'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '153'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:14
User entered '78'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 18:29:36

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43

US3232050

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43

US3232050

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:06:11
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:29:49

US3232050

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:06:11
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:29:49
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:26
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:29
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:26
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'Outdoor service provider'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:26
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:07:29
	(b) (4), (b) (6)	
User entered '0'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:26
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:26
	(b) (4)	

US3232050

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:07:29
User entered 'resident in a community with ongoing person to person transmission'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:26

US3232050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:01
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:39
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:01
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:39
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:01
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:39
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'VISIT1'	(b) (4), (b) (6) System	14 Aug 2020 18:31:39

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
User entered '14 AUG 2020'	RWS_ENDPOINT	14 Aug 2020 16:39:36
	ENDPOINT (b) (4)	
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:33:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:33:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:39:36
User entered '186212' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 16:39:36

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
User entered '>=65 years (3)'	RWS_ENDPOINT	14 Aug 2020 16:39:36
	ENDPOINT (b) (4)	
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:07
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:59

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:07
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:31:59

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:59
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:59
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:07
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:31:59
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:42

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:44:30
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:41:37
User entered 'No (N)'	Rambod Rouhbakhsh	01 Dec 2020 19:27:25
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:21:01
Amendment Manager inserted this DataPoint.	Jerrica Sullivan (b) (4)	19 Sep 2020 07:18:01
	(b) (4)	
	System	
	System	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:15
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:12
User entered '174' cm	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:17
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:17
User entered '99.6' kg	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:15
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:12
User entered '174' cm	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:17
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:17
User entered '99.6' kg	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '11:05'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '14 Aug 2020 11:05'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '98.0' F	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '88'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '17'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '153'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '78'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:15
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:16
User entered missing code ND - Not Done; reason for change Per Query Resolution	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:12
User entered '174' cm	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:17
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'corrected' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:34:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 15:19:17
User entered '99.6' kg	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Aug 2020 12:03:06
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 20:55:48
User closed query 'Data is required. Please provide.' System (Site from System).		14 Aug 2020 20:55:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Aug 2020 20:55:48
User entered '12:52' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:48
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 20:55:26
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User entered '14 Aug 2020 12:52'	System	14 Aug 2020 20:55:48
User entered empty.	System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '98.1' F	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '77'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'bpm'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '18'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:08:26
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 11:35:32
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'subject has a history of hypertension and takes medication. ncs' (Site from System).	Adreanna Pou (b) (4) (b) (4)	28 Aug 2020 17:35:25
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Aug 2020 20:55:26
User entered '170'	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:26
	(b) (4), (b) (6)	
User entered '70'	Jerrica Sullivan (b) (4)	14 Aug 2020 20:55:26
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	14 Aug 2020 20:55:26

US3232050

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:35
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:48:02
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:35
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:48:02
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered '12:05'	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '14 Aug 2020 12:05'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
	(b) (4), (b) (6)	
User entered 'Left Arm (LEFT ARM)'	Adreanna Pou (b) (4)	14 Aug 2020 17:21:19
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:08:42
User entered 'ONCE'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:21:13
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:48:58
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:21:13
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:48:58
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:21:13
	(b) (4), (b) (6)	
User entered '11:43'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:48:58
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '14 Aug 2020 11:43'	(b) (4), (b) (6) System	14 Aug 2020 18:48:58

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User closed query 'In subject source, please answer question one; Was the Nasopharyngeal Swab collected at this visit per protocol? Please tick the appropriate yes or no box.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	17 Mar 2021 15:54:48
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	18 Feb 2021 15:41:37
Query 'In subject source, please answer question one; Was the Nasopharyngeal Swab collected at this visit per protocol? Please tick the appropriate yes or no box.' answered with 'corrected' (Site from CRA).	Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 19:05:44
User opened query 'In subject source, please answer question one; Was the Nasopharyngeal Swab collected at this visit per protocol? Please tick the appropriate yes or no box.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 17:20:57
Query 'Please update source data sheet with a tick in the appropriate box indicating whether swab was collected.' canceled (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 17:19:50
User opened query 'Please update source data sheet with a tick in the appropriate box indicating whether swab was collected.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 17:19:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 17:09:44
User entered '14 Aug 2020'	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:49:25

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:49:25

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:09:44
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:25
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:09:44
	(b) (4), (b) (6)	
User entered '11:10'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:25
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '14 Aug 2020 11:10'	(b) (4), (b) (6) System	14 Aug 2020 18:49:25

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:49:25

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:16
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:41:37
DataPoint Un-verified.	Rambod Rouhbakhsh	05 Oct 2020 17:17:30
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:09:44
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:25
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:16
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:41:37
DataPoint Un-verified.	Rambod Rouhbakhsh	05 Oct 2020 17:17:30
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:09:44
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:25
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered empty.	(b) (4), (b) (6) System	14 Aug 2020 18:49:25

US3232050

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:21:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:32
	(b) (4)	

US3232050

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	14 Aug 2020 18:49:32

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:30:33', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3674ab23-359a-41be-956d-a5b15fe771b5' User entered 'Yes (Y)'	System	14 Aug 2020 17:31:10
	System	14 Aug 2020 17:31:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:30:53', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3674ab23-359a-41be-956d-a5b15fe771b5' User entered '98.1'	System	14 Aug 2020 17:31:10
	System	14 Aug 2020 17:31:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:30:57', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3674ab23-359a-41be-956d-a5b15fe771b5'	System	14 Aug 2020 17:31:10
User entered 'No (N)'	System	14 Aug 2020 17:31:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:08', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3674ab23-359a-41be-956d-a5b15fe771b5' User entered '14 Aug 2020 12:31'	System	14 Aug 2020 17:31:10
	System	14 Aug 2020 17:31:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 12:25'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
User entered '14 Aug 2020 14:55'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:16:12', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4814c925-353e-4c6c-bacc-b8b6b0835209' User entered 'Yes (Y)'	System	15 Aug 2020 12:16:59
	System	15 Aug 2020 12:16:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:16:30', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4814c925-353e-4c6c-bacc-b8b6b0835209' User entered '96.6'	System	15 Aug 2020 12:16:59
	System	15 Aug 2020 12:16:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:16:45', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4814c925-353e-4c6c-bacc-b8b6b0835209'	System	15 Aug 2020 12:16:59
User entered 'No (N)'	System	15 Aug 2020 12:16:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:16:55', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4814c925-353e-4c6c-bacc-b8b6b0835209'	System	15 Aug 2020 12:16:59
User entered '15 Aug 2020 07:16'	System	15 Aug 2020 12:16:59

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 2'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:14:36', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '127c1649-362f-4938-a3ed-368546fd33ca' User entered 'Yes (Y)'	System	16 Aug 2020 14:15:06
	System	16 Aug 2020 14:15:06

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:14:44', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '127c1649-362f-4938-a3ed-368546fd33ca' User entered '98.6'	System	16 Aug 2020 14:15:06
	System	16 Aug 2020 14:15:06

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:14:55', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '127c1649-362f-4938-a3ed-368546fd33ca' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 14:15:06
	System	16 Aug 2020 14:15:06

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:15:04', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '127c1649-362f-4938-a3ed-368546fd33ca' User entered '16 Aug 2020 09:15'	System	16 Aug 2020 14:15:06
	System	16 Aug 2020 14:15:06

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 3'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:52:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3fa8b1f8-b23e-45cb-a944-2173ac1ff59c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 20:52:50
	System	16 Aug 2020 20:52:50

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:52:37', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3fa8b1f8-b23e-45cb-a944-2173ac1ff59c' User entered '98.8'	System	16 Aug 2020 20:52:50
	System	16 Aug 2020 20:52:50

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:52:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3fa8b1f8-b23e-45cb-a944-2173ac1ff59c' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 20:52:50
	System	16 Aug 2020 20:52:50

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:52:49', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3fa8b1f8-b23e-45cb-a944-2173ac1ff59c' User entered '16 Aug 2020 15:52'	System	16 Aug 2020 20:52:50
	System	16 Aug 2020 20:52:50

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 4'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:14', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'f7a1a8e2-d314-46b2-ae8c-9f01732462ce' User entered 'Yes (Y)'	System	17 Aug 2020 17:21:41
	System	17 Aug 2020 17:21:41

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'f7a1a8e2-d314-46b2-ae8c-9f01732462ce' User entered '97.8'	(b) (4), (b) (6) System	17 Aug 2020 17:21:41
	System	17 Aug 2020 17:21:41

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:32', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'f7a1a8e2-d314-46b2-ae8c-9f01732462ce' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:21:41
	System	17 Aug 2020 17:21:41

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'f7a1a8e2-d314-46b2-ae8c-9f01732462ce' User entered '17 Aug 2020 12:21'	System	17 Aug 2020 17:21:41
	System	17 Aug 2020 17:21:41

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 5'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:23:04', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5eaa1995-471a-4cc8-b646-cf15be26a3ad' User entered 'Yes (Y)'	System	18 Aug 2020 20:25:24
	System	18 Aug 2020 20:25:24

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:24:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5eaa1995-471a-4cc8-b646-cf15be26a3ad' User entered '98.3'	System	18 Aug 2020 20:25:24
	System	18 Aug 2020 20:25:24

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:24:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5eaa1995-471a-4cc8-b646-cf15be26a3ad'	System	18 Aug 2020 20:25:24
User entered 'No (N)'	System	18 Aug 2020 20:25:24

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5eaa1995-471a-4cc8-b646-cf15be26a3ad' User entered '18 Aug 2020 15:25'	System	18 Aug 2020 20:25:24
	System	18 Aug 2020 20:25:24

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 6'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:40:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0a116be1-e085-4ff3-b1c1-21bcbdb523ac' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 20:41:10
	System	19 Aug 2020 20:41:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:40:57', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0a116be1-e085-4ff3-b1c1-21bcbdb523ac' User entered '98.0'	System	19 Aug 2020 20:41:10
	System	19 Aug 2020 20:41:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:01', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0a116be1-e085-4ff3-b1c1-21bcbdb523ac'	System	19 Aug 2020 20:41:10
User entered 'No (N)'	System	19 Aug 2020 20:41:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0a116be1-e085-4ff3-b1c1-21bcbdb523ac' User entered '19 Aug 2020 15:41'	System	19 Aug 2020 20:41:10
	System	19 Aug 2020 20:41:10

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 7'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:55:16', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'bfb1fa46-9125-41c7-a0b8-7e5005065878'	System	21 Aug 2020 13:55:45
User entered 'Yes (Y)'	System	21 Aug 2020 13:55:45

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:55:34', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'bfb1fa46-9125-41c7-a0b8-7e5005065878' User entered '97.8'	System	21 Aug 2020 13:55:45
	System	21 Aug 2020 13:55:45

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:55:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'bfb1fa46-9125-41c7-a0b8-7e5005065878' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:55:45
	System	21 Aug 2020 13:55:45

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:55:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'bfb1fa46-9125-41c7-a0b8-7e5005065878'	System	21 Aug 2020 13:55:45
User entered '21 Aug 2020 08:55'	System	21 Aug 2020 13:55:45

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce80d7c2-decf-4d51-8a36-7cb4283596da' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 17:32:42
	System	14 Aug 2020 17:32:42

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce80d7c2-decf-4d51-8a36-7cb4283596da' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 17:32:42
	System	14 Aug 2020 17:32:42

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:30', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce80d7c2-decf-4d51-8a36-7cb4283596da' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 17:32:42
	System	14 Aug 2020 17:32:42

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:34', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce80d7c2-decf-4d51-8a36-7cb4283596da' User entered 'None (1)'	System	14 Aug 2020 17:32:42
	System	14 Aug 2020 17:32:42

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:39', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce80d7c2-decf-4d51-8a36-7cb4283596da' User entered '14 Aug 2020 12:32'	System	14 Aug 2020 17:32:42
	System	14 Aug 2020 17:32:42

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 12:25'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 14:55'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:19:10', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0f7c768a-adde-432c-9cab-c6bd21445123'	(b) (4), (b) (6)	
	System	15 Aug 2020 12:19:59
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 12:19:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:19:14', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0f7c768a-adde-432c-9cab-c6bd21445123'	System	15 Aug 2020 12:19:59
User entered 'No (N)'	System	15 Aug 2020 12:19:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:19:18', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0f7c768a-adde-432c-9cab-c6bd21445123' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 12:19:59
	System	15 Aug 2020 12:19:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:19:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0f7c768a-adde-432c-9cab-c6bd21445123'	System	15 Aug 2020 12:19:59
User entered 'None (1)'	System	15 Aug 2020 12:19:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:19:56', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0f7c768a-adde-432c-9cab-c6bd21445123' User entered '15 Aug 2020 07:19'	System	15 Aug 2020 12:19:59
	System	15 Aug 2020 12:19:59

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 15:50'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 2'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:09', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '736467d7-2581-4dab-89f6-30ae13dcb2c1' User entered 'None (1)'	System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '736467d7-2581-4dab-89f6-30ae13dcb2c1' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:18', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '736467d7-2581-4dab-89f6-30ae13dcb2c1' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:26', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '736467d7-2581-4dab-89f6-30ae13dcb2c1' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:40', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '736467d7-2581-4dab-89f6-30ae13dcb2c1' User entered '16 Aug 2020 09:19'	System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 3'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:52:58', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '572c9f23-9c98-42d6-bd1b-1c120b529055'	(b) (4), (b) (6)	
	System	16 Aug 2020 20:53:21
User entered 'None (1)'	System	16 Aug 2020 20:53:21

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:02', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '572c9f23-9c98-42d6-bd1b-1c120b529055' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 20:53:21
	System	16 Aug 2020 20:53:21

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:05', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '572c9f23-9c98-42d6-bd1b-1c120b529055'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Aug 2020 20:53:21

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:10', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '572c9f23-9c98-42d6-bd1b-1c120b529055' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 20:53:21
	System	16 Aug 2020 20:53:21

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:17', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '572c9f23-9c98-42d6-bd1b-1c120b529055' User entered '16 Aug 2020 15:53'	(b) (4), (b) (6) System	16 Aug 2020 20:53:21
	System	16 Aug 2020 20:53:21

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 4'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:51', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '14b828be-1de6-4949-a2e0-70454b39ab36' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 17:22:20
	System	17 Aug 2020 17:22:20

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:21:55', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '14b828be-1de6-4949-a2e0-70454b39ab36' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 17:22:20
	System	17 Aug 2020 17:22:20

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:02', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '14b828be-1de6-4949-a2e0-70454b39ab36' User entered 'No (N)'	System	17 Aug 2020 17:22:20
	System	17 Aug 2020 17:22:20

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '14b828be-1de6-4949-a2e0-70454b39ab36'	(b) (4), (b) (6)	
User entered 'None (1)'	System	17 Aug 2020 17:22:20

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:18', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '14b828be-1de6-4949-a2e0-70454b39ab36'	System	17 Aug 2020 17:22:20
User entered '17 Aug 2020 12:22'	System	17 Aug 2020 17:22:20

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 5'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:31', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3a275806-3ebd-4d64-a66c-a0e5c6aba8a8'	(b) (4), (b) (6)	
	System	18 Aug 2020 20:25:53
User entered 'None (1)'	System	18 Aug 2020 20:25:53

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:35', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3a275806-3ebd-4d64-a66c-a0e5c6aba8a8'	System	18 Aug 2020 20:25:53
User entered 'No (N)'	System	18 Aug 2020 20:25:53

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3a275806-3ebd-4d64-a66c-a0e5c6aba8a8' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 20:25:53
	System	18 Aug 2020 20:25:53

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3a275806-3ebd-4d64-a66c-a0e5c6aba8a8'	(b) (4), (b) (6)	
	System	18 Aug 2020 20:25:53
User entered 'None (1)'	System	18 Aug 2020 20:25:53

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:50', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '3a275806-3ebd-4d64-a66c-a0e5c6aba8a8'	System	18 Aug 2020 20:25:53
User entered '18 Aug 2020 15:25'	System	18 Aug 2020 20:25:53

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 6'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:15', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4a64ce90-8108-4329-b5d9-33462540fc17' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 20:41:44
	System	19 Aug 2020 20:41:44

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:19', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4a64ce90-8108-4329-b5d9-33462540fc17' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 20:41:44
	System	19 Aug 2020 20:41:44

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4a64ce90-8108-4329-b5d9-33462540fc17' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 20:41:44
	System	19 Aug 2020 20:41:44

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4a64ce90-8108-4329-b5d9-33462540fc17' User entered 'None (1)'	System	19 Aug 2020 20:41:44
	System	19 Aug 2020 20:41:44

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:40', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '4a64ce90-8108-4329-b5d9-33462540fc17' User entered '19 Aug 2020 15:41'	System	19 Aug 2020 20:41:44
	System	19 Aug 2020 20:41:44

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 7'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:53:33', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '7f094c40-bb09-4d39-bb72-7fad329f10fb' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 13:53:56
	System	21 Aug 2020 13:53:56

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:53:37', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '7f094c40-bb09-4d39-bb72-7fad329f10fb' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:53:56
	System	21 Aug 2020 13:53:56

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:53:40', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '7f094c40-bb09-4d39-bb72-7fad329f10fb' User entered 'No (N)'	System	21 Aug 2020 13:53:56
	System	21 Aug 2020 13:53:56

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:53:44', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '7f094c40-bb09-4d39-bb72-7fad329f10fb' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 13:53:56
	System	21 Aug 2020 13:53:56

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:53:52', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '7f094c40-bb09-4d39-bb72-7fad329f10fb' User entered '21 Aug 2020 08:53'	(b) (4), (b) (6) System	21 Aug 2020 13:53:56
	System	21 Aug 2020 13:53:56

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553' User entered 'None (0)'	System	14 Aug 2020 17:32:18
	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:45', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 17:32:18
	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:48', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553' User entered 'None (0)'	System	14 Aug 2020 17:32:18
	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:52', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553' User entered 'None (0)'	System	14 Aug 2020 17:32:18
	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:55', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553'	System	14 Aug 2020 17:32:18
User entered 'None (0)'	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:31:58', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553'	System	14 Aug 2020 17:32:18
User entered 'None (0)'	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:03', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553'	System	14 Aug 2020 17:32:18
User entered 'No (N)'	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-14T12:32:08', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'a68cb1c7-2f73-4c59-b283-60e2a1509553'	System	14 Aug 2020 17:32:18
User entered '14 Aug 2020 12:32'	System	14 Aug 2020 17:32:18

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 12:25'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
User entered '14 Aug 2020 14:55'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'None (0)'	System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:11', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'None (0)'	System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:15', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:18', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'None (0)'	System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b'	System	15 Aug 2020 12:20:42
User entered 'None (0)'	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:31', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b' User entered 'No (N)'	System	15 Aug 2020 12:20:42
	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-15T07:20:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '2e707efd-740f-4278-ab52-aa7c8e57695b'	System	15 Aug 2020 12:20:42
User entered '15 Aug 2020 07:20'	System	15 Aug 2020 12:20:42

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Aug 2020 15:50'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 2'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:47', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:52', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:19:57', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:20:00', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:20:04', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:20:08', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'None (0)'	System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:20:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 14:20:28
	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T09:20:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5d26db70-5823-4e58-a1f0-faab25e9a777'	System	16 Aug 2020 14:20:28
User entered '16 Aug 2020 09:20'	System	16 Aug 2020 14:20:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 3'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123'	(b) (4), (b) (6)	
User entered 'None (0)'	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123'	System	16 Aug 2020 20:54:02
User entered 'None (0)'	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:30', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123' User entered 'None (0)'	System	16 Aug 2020 20:54:02
	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:33', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 20:54:02
	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:36', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123'	System	16 Aug 2020 20:54:02
User entered 'None (0)'	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123'	System	16 Aug 2020 20:54:02
User entered 'None (0)'	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:53:49', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123'	(b) (4), (b) (6)	
	System	16 Aug 2020 20:54:02
User entered 'No (N)'	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-16T15:54:00', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c2f48725-69af-45e5-a5e7-4b34c3ec1123' User entered '16 Aug 2020 15:54'	(b) (4), (b) (6) System	16 Aug 2020 20:54:02
	System	16 Aug 2020 20:54:02

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 4'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:25', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:28', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:32', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:35', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:40', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered 'None (0)'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:44', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd'	System	17 Aug 2020 17:22:49
User entered 'No (N)'	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-17T12:22:47', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '72ce82e4-1887-4102-bcce-616bf971bacd' User entered '17 Aug 2020 12:22'	System	17 Aug 2020 17:22:49
	System	17 Aug 2020 17:22:49

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 5'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:25:59', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 20:26:28
	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:02', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625'	System	18 Aug 2020 20:26:28
User entered 'None (0)'	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:04', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625'	System	18 Aug 2020 20:26:28
User entered 'None (0)'	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:08', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 20:26:28
	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:10', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625' User entered 'None (0)'	System	18 Aug 2020 20:26:28
	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625' User entered 'None (0)'	System	18 Aug 2020 20:26:28
	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:17', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 20:26:28
	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-18T15:26:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd872d0ae-c7f1-43b4-86a6-dfd63c917625'	System	18 Aug 2020 20:26:28
User entered '18 Aug 2020 15:26'	System	18 Aug 2020 20:26:28

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 6'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:41:54', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:00', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:04', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:10', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'None (0)'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:29', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-19T15:42:40', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd6667663-0330-4398-95db-eaf081157eac' User entered '19 Aug 2020 15:42'	System	19 Aug 2020 20:42:44
	System	19 Aug 2020 20:42:44

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 7'	System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:55:58', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:03', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:08', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:11', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:14', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'None (0)'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:19', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-08-21T08:56:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd11eac42-63c5-46b9-ae9d-cd8d8beb8ea5' User entered '21 Aug 2020 08:56'	System	21 Aug 2020 13:56:27
	System	21 Aug 2020 13:56:27

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Aug 2020 20:56:40
	(b) (4)	

US3232050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:39
	(b) (4), (b) (6)	
User entered '21 Aug 2020'	Adreanna Pou (b) (4)	21 Aug 2020 20:56:40
	(b) (4)	

US3232050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:39
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	21 Aug 2020 20:56:40
	(b) (4)	

US3232050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:39
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	21 Aug 2020 20:56:40
	(b) (4)	

US3232050

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:44
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	21 Aug 2020 20:56:44
	(b) (4)	

US3232050

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 20:56:44

US3232050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:51
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	28 Aug 2020 22:35:12
	(b) (4)	

US3232050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:51
	(b) (4), (b) (6)	
User entered '28 Aug 2020'	Jerrica Sullivan (b) (4)	28 Aug 2020 22:35:12
	(b) (4)	

US3232050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:51
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	28 Aug 2020 22:35:12
	(b) (4)	

US3232050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:51
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	28 Aug 2020 22:35:12
	(b) (4)	

US3232050

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:41:56
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Sep 2020 12:41:21
	(b) (4)	

US3232050

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	04 Sep 2020 12:41:21

US3232050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:12
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Sep 2020 15:07:43
	(b) (4)	

US3232050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:12
	(b) (4), (b) (6)	
User entered '4 Sep 2020'	Jerrica Sullivan (b) (4)	04 Sep 2020 15:07:43
	(b) (4)	

US3232050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:12
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	04 Sep 2020 15:07:43
	(b) (4)	

US3232050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:12
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	04 Sep 2020 15:07:43
	(b) (4)	

US3232050

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Sep 2020 15:07:51
	(b) (4)	

US3232050

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	04 Sep 2020 15:07:51

US3232050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:43
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:23:13
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:43
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:23:13
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:43
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	18 Sep 2020 23:23:13
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'VISIT2'	(b) (4), (b) (6) System	18 Sep 2020 23:23:13

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '10:04'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '11 Sep 2020 10:04'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '98' F	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '96'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'bpm'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '22'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'breaths/min'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '143'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:41:37
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 12:26:41
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	02 Oct 2020 16:10:19
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		18 Sep 2020 23:25:47
User entered '54'	Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '11:14'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '11 Sep 2020 11:14'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '97.5' F	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '85'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'bpm'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '18'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'breaths/min'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '146'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:50
	(b) (4), (b) (6)	
User entered '76'	Adreanna Pou (b) (4)	18 Sep 2020 23:25:47
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'mmHg'	(b) (4), (b) (6) System	18 Sep 2020 23:25:47

US3232050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:26:15
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:11:57
	(b) (4), (b) (6)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 23:26:22
User entered '11 Sep 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4)	18 Sep 2020 23:26:22
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 23:26:15
User entered '18 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:26:15
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered '10:58'	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '11 Sep 2020 10:58'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
	(b) (4), (b) (6)	
User entered 'Left Arm (LEFT ARM)'	Adreanna Pou (b) (4)	18 Sep 2020 23:22:53
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:04
User entered 'ONCE'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:14
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:26:56
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:14
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:26:56
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:14
	(b) (4), (b) (6)	
User entered '10:05'	Adreanna Pou (b) (4)	18 Sep 2020 23:26:56
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '11 Sep 2020 10:05'	(b) (4), (b) (6) System	18 Sep 2020 23:26:56

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:26
	(b) (4), (b) (6)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:29:38
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:29:38

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:29
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:29:38
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:29
	(b) (4), (b) (6)	
User entered '10:05'	Adreanna Pou (b) (4)	18 Sep 2020 23:29:38
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '11 Sep 2020 10:05'	(b) (4), (b) (6) System	18 Sep 2020 23:29:38

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:29:38

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:47:47
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:41:37
User entered 'No (N)'	Rambod Rouhbakhsh	18 Sep 2020 23:29:38
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:47:47
User signature succeeded.	(b) (4), (b) (6)	18 Feb 2021 15:41:37
User entered empty.	Rambod Rouhbakhsh	18 Sep 2020 23:29:38
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered empty.	(b) (4), (b) (6) System	18 Sep 2020 23:29:38

US3232050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:38
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:29:43
	(b) (4)	

US3232050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '1'	(b) (4), (b) (6) System	18 Sep 2020 23:29:43

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 23:22:53
	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 11:18'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 13:48'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 14:43'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	18 Sep 2020 23:22:53
	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 3'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 4'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 5'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 6'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 7'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
	System	18 Sep 2020 23:22:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 11:18'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 13:48'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
	System	18 Sep 2020 23:22:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 14:43'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 2'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 3'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 4'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 5'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 6'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 7'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
	System	18 Sep 2020 23:22:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 11:18'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 13:48'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '11 Sep 2020 14:43'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 2'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 3'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 4'	System	18 Sep 2020 23:22:53
	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 5'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 6'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	18 Sep 2020 23:22:53
User entered 'Day 7'	System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:17:12

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 23:22:53

US3232050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:47
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	18 Sep 2020 23:30:03
	(b) (4)	

US3232050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:47
	(b) (4), (b) (6)	
User entered '18 Sep 2020'	Adreanna Pou (b) (4)	18 Sep 2020 23:30:03
	(b) (4)	

US3232050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:47
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	18 Sep 2020 23:30:03
	(b) (4)	

US3232050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 15:37:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:12:47
User entered empty.	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	18 Sep 2020 23:30:03

US3232050

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:37:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:41
	(b) (4)	

US3232050

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 21:44:41

US3232050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:43
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:51
	(b) (4)	

US3232050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:43
	(b) (4), (b) (6)	
User entered '25 Sep 2020'	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:51
	(b) (4)	

US3232050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:43
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:51
	(b) (4)	

US3232050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:43
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:51
	(b) (4)	

US3232050

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:42:48
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	25 Sep 2020 21:44:55
	(b) (4)	

US3232050

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 21:44:55

US3232050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:23:00
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:10:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	07 Oct 2020 15:43:19
	(b) (4)	

US3232050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
Protocol deviation created: visit was out of window + 2 days Class: Incl/Excl Criteria not met Code: Deviation.	(b) (4), (b) (6)	02 Nov 2020 17:41:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:23:00
	(b) (4), (b) (6)	
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 09:44:02
	(b) (4), (b) (6)	
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'devation noted' (Site from System).	Adreanna Pou (b) (4)	07 Oct 2020 15:44:22
	(b) (4)	
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 15:43:19
User entered '6 Oct 2020'	Adreanna Pou (b) (4)	07 Oct 2020 15:43:19
	(b) (4)	

US3232050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:23:00
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	07 Oct 2020 15:43:19
	(b) (4)	

US3232050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:23:00
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	07 Oct 2020 15:43:19
	(b) (4)	

US3232050

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:23:12
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	07 Oct 2020 15:44:27
	(b) (4)	

US3232050

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	07 Oct 2020 15:44:27

US3232050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:25:34
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 18:34:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:25:34
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 18:34:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:25:34
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	09 Oct 2020 18:34:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered 'VISIT3'	(b) (4), (b) (6) System	09 Oct 2020 18:34:42

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:43:41
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:43:43
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:43:44
	(b) (4), (b) (6)	
User entered '10:10'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered '9 Oct 2020 10:10'	(b) (4), (b) (6) System	09 Oct 2020 18:35:15

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:43:46
	(b) (4), (b) (6)	
User entered '98.6' F	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered '85'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered 'bpm'	(b) (4), (b) (6) System	09 Oct 2020 18:35:15

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered '20'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 18:35:15

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered '172'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 18:35:15

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:12
	(b) (4), (b) (6)	
User entered '75'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:15
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 18:35:15

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:46
	(b) (4), (b) (6)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:24
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:27
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:24
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:27
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:46
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:46
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:46
	(b) (4), (b) (6)	
User entered '10:17'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:42
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '9 Oct 2020 10:17'	(b) (4), (b) (6) System	09 Oct 2020 18:35:42

US3232050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 17:44:54
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 18:35:51
	(b) (4)	

US3232050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered '1'	(b) (4), (b) (6) System	09 Oct 2020 18:35:51

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 64'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-18T10:32:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '366460e8-daaf-4376-814d-3fdc1de195b7'	(b) (4), (b) (6)	
	System	18 Oct 2020 15:33:02
User entered 'No (N)'	System	18 Oct 2020 15:33:02

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-18T10:32:48', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '366460e8-daaf-4376-814d-3fdc1de195b7'	(b) (4), (b) (6)	
	System	18 Oct 2020 15:33:02
User entered 'No (N)'	System	18 Oct 2020 15:33:02

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-18T10:33:00', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '366460e8-daaf-4376-814d-3fdc1de195b7' User entered '18 Oct 2020 10:33:00'	(b) (4), (b) (6) System	18 Oct 2020 15:33:02
	System	18 Oct 2020 15:33:02

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 71'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-21T11:14:39', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c1703b79-7fda-4435-bdda-ecc552267434'	(b) (4), (b) (6)	
	System	21 Oct 2020 16:14:52
User entered 'No (N)'	System	21 Oct 2020 16:14:52

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-21T11:14:43', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c1703b79-7fda-4435-bdda-ecc552267434'	(b) (4), (b) (6)	
	System	21 Oct 2020 16:14:52
User entered 'No (N)'	System	21 Oct 2020 16:14:52

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-21T11:14:49', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c1703b79-7fda-4435-bdda-ecc552267434' User entered '21 Oct 2020 11:14:49'	(b) (4), (b) (6) System	21 Oct 2020 16:14:52
	System	21 Oct 2020 16:14:52

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 78'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-28T19:24:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '056f76fb-0916-454b-a5d4-69d51c6f4947'	(b) (4), (b) (6)	
	System	29 Oct 2020 00:24:45
User entered 'No (N)'	System	29 Oct 2020 00:24:45

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-28T19:24:31', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '056f76fb-0916-454b-a5d4-69d51c6f4947'	(b) (4), (b) (6)	
	System	29 Oct 2020 00:24:45
User entered 'No (N)'	System	29 Oct 2020 00:24:45

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-10-28T19:24:42', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '056f76fb-0916-454b-a5d4-69d51c6f4947' User entered '28 Oct 2020 19:24:42'	System	29 Oct 2020 00:24:45
	System	29 Oct 2020 00:24:45

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 92'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:27:38
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered 'Day 99'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-11-18T08:13:46', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '85c655ef-9840-41da-be34-20da6a195530' User entered 'No (N)'	System	18 Nov 2020 14:14:09
	System	18 Nov 2020 14:14:09

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-11-18T08:13:56', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '85c655ef-9840-41da-be34-20da6a195530' User entered 'No (N)'	(b) (4), (b) (6) System	18 Nov 2020 14:14:09
	System	18 Nov 2020 14:14:09

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-11-18T08:14:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '85c655ef-9840-41da-be34-20da6a195530' User entered '18 Nov 2020 08:14:07'	System	18 Nov 2020 14:14:09
	System	18 Nov 2020 14:14:09

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:21:19

US3232050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:12
	(b) (4), (b) (6)	
Data entry locked.	System	14 Aug 2020 17:21:19
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:21:19

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-03T17:44:20', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'dcac089d-9680-419f-be80-a11b9a070cfc'	System	03 Dec 2020 23:44:37
User entered 'No (N)'	System	03 Dec 2020 23:44:37

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-03T17:44:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'dcac089d-9680-419f-be80-a11b9a070cfc'	System	03 Dec 2020 23:44:37
User entered 'No (N)'	System	03 Dec 2020 23:44:37

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-03T17:44:34', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'dcac089d-9680-419f-be80-a11b9a070cfc' User entered '03 Dec 2020 17:44:34'	System	03 Dec 2020 23:44:37
	System	03 Dec 2020 23:44:37

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-06T09:11:05', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '578057a1-35ec-434a-ab94-63d2aaecf62f' User entered 'No (N)'	System	06 Dec 2020 15:11:29
	System	06 Dec 2020 15:11:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-06T09:11:17', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '578057a1-35ec-434a-ab94-63d2aaecf62f' User entered 'No (N)'	System	06 Dec 2020 15:11:29
	System	06 Dec 2020 15:11:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-06T09:11:26', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '578057a1-35ec-434a-ab94-63d2aaecf62f' User entered '06 Dec 2020 09:11:26'	System	06 Dec 2020 15:11:29
	System	06 Dec 2020 15:11:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-13T15:13:38', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5446662a-b32c-4a35-80f1-bb2b59901e48' User entered 'No (N)'	System	13 Dec 2020 21:13:57
	System	13 Dec 2020 21:13:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-13T15:13:44', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5446662a-b32c-4a35-80f1-bb2b59901e48' User entered 'No (N)'	System	13 Dec 2020 21:13:57
	System	13 Dec 2020 21:13:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-13T15:13:54', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5446662a-b32c-4a35-80f1-bb2b59901e48' User entered '13 Dec 2020 15:13:54'	System	13 Dec 2020 21:13:57
	System	13 Dec 2020 21:13:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-21T17:01:51', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '71b610b4-9301-48b3-9951-dedd4ea22815'	System	21 Dec 2020 23:02:06
User entered 'No (N)'	System	21 Dec 2020 23:02:06

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-21T17:01:56', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '71b610b4-9301-48b3-9951-dedd4ea22815'	System	21 Dec 2020 23:02:06
User entered 'No (N)'	System	21 Dec 2020 23:02:06

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-21T17:02:03', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '71b610b4-9301-48b3-9951-dedd4ea22815'	System	21 Dec 2020 23:02:06
User entered '21 Dec 2020 17:02:03'	System	21 Dec 2020 23:02:06

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-28T21:11:36', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'fa3e4e19-a489-4340-8cc1-993fcd4d786d' User entered 'No (N)'	System	29 Dec 2020 03:11:51
	System	29 Dec 2020 03:11:51

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-28T21:11:41', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'fa3e4e19-a489-4340-8cc1-993fcd4d786d' User entered 'No (N)'	System	29 Dec 2020 03:11:51
	System	29 Dec 2020 03:11:51

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2020-12-28T21:11:46', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'fa3e4e19-a489-4340-8cc1-993fcd4d786d' User entered '28 Dec 2020 21:11:46'	System	29 Dec 2020 03:11:51
	System	29 Dec 2020 03:11:51

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-03T08:34:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c7bc99c5-d324-4e27-99f0-9ff303a174c6'	System	03 Jan 2021 14:34:29
User entered 'No (N)'	System	03 Jan 2021 14:34:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-03T08:34:15', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c7bc99c5-d324-4e27-99f0-9ff303a174c6'	System	03 Jan 2021 14:34:29
User entered 'No (N)'	System	03 Jan 2021 14:34:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-03T08:34:26', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'c7bc99c5-d324-4e27-99f0-9ff303a174c6' User entered '03 Jan 2021 08:34:26'	System	03 Jan 2021 14:34:29
	System	03 Jan 2021 14:34:29

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-10T09:26:53', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0ad6a52c-3a4b-41df-9beb-77e63a06c486'	System	10 Jan 2021 15:27:09
User entered 'No (N)'	System	10 Jan 2021 15:27:09

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-10T09:27:00', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0ad6a52c-3a4b-41df-9beb-77e63a06c486'	System	10 Jan 2021 15:27:09
User entered 'No (N)'	System	10 Jan 2021 15:27:09

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-10T09:27:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '0ad6a52c-3a4b-41df-9beb-77e63a06c486' User entered '10 Jan 2021 09:27:07'	System	10 Jan 2021 15:27:09
	System	10 Jan 2021 15:27:09

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-17T12:06:53', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce496f34-89e0-4232-9f5f-3691f18abcef' User entered 'No (N)'	System	17 Jan 2021 18:07:08
	System	17 Jan 2021 18:07:08

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-17T12:06:59', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce496f34-89e0-4232-9f5f-3691f18abcef' User entered 'No (N)'	System	17 Jan 2021 18:07:08

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-17T12:07:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ce496f34-89e0-4232-9f5f-3691f18abcef' User entered '17 Jan 2021 12:07:06'	System	17 Jan 2021 18:07:08

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-24T15:39:58', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '63e85e74-07f7-4e6b-b62d-f7a4009b9a8a' User entered 'No (N)'	System	24 Jan 2021 21:40:16
	System	24 Jan 2021 21:40:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-24T15:40:05', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '63e85e74-07f7-4e6b-b62d-f7a4009b9a8a' User entered 'No (N)'	System	24 Jan 2021 21:40:16
	System	24 Jan 2021 21:40:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-01-24T15:40:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '63e85e74-07f7-4e6b-b62d-f7a4009b9a8a' User entered '24 Jan 2021 15:40:13'	System	24 Jan 2021 21:40:16
	System	24 Jan 2021 21:40:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-01T17:46:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'b45bb204-6e3d-4bac-a0bd-a336d2947701'	System	01 Feb 2021 23:46:23
User entered 'No (N)'	System	01 Feb 2021 23:46:23

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-01T17:46:12', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'b45bb204-6e3d-4bac-a0bd-a336d2947701'	System	01 Feb 2021 23:46:23
User entered 'No (N)'	System	01 Feb 2021 23:46:23

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-01T17:46:16', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'b45bb204-6e3d-4bac-a0bd-a336d2947701'	System	01 Feb 2021 23:46:23
User entered '01 Feb 2021 17:46:16'	System	01 Feb 2021 23:46:23

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-07T19:11:19', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8c92354a-2c66-4535-b1b4-a5b5f8779aae' User entered 'No (N)'	System	08 Feb 2021 01:11:36
	System	08 Feb 2021 01:11:36

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-07T19:11:26', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8c92354a-2c66-4535-b1b4-a5b5f8779aae' User entered 'No (N)'	System	08 Feb 2021 01:11:36
	System	08 Feb 2021 01:11:36

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-07T19:11:32', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8c92354a-2c66-4535-b1b4-a5b5f8779aae' User entered '07 Feb 2021 19:11:32'	System	08 Feb 2021 01:11:36
	System	08 Feb 2021 01:11:36

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-15T09:00:02', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '726bba10-2f0b-497e-baa2-338a8016664f' User entered 'No (N)'	System	15 Feb 2021 15:00:17
	System	15 Feb 2021 15:00:17

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-15T09:00:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '726bba10-2f0b-497e-baa2-338a8016664f' User entered 'No (N)'	System	15 Feb 2021 15:00:17
	System	15 Feb 2021 15:00:17

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-15T09:00:14', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '726bba10-2f0b-497e-baa2-338a8016664f' User entered '15 Feb 2021 09:00:14'	System	15 Feb 2021 15:00:17
	System	15 Feb 2021 15:00:17

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-23T07:33:58', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '29bb5e30-db60-47d5-bfd5-b152232d6798'	System	23 Feb 2021 13:34:14
User entered 'No (N)'	System	23 Feb 2021 13:34:14

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-23T07:34:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '29bb5e30-db60-47d5-bfd5-b152232d6798'	System	23 Feb 2021 13:34:14
User entered 'No (N)'	System	23 Feb 2021 13:34:14

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-23T07:34:11', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '29bb5e30-db60-47d5-bfd5-b152232d6798'	System	23 Feb 2021 13:34:14
User entered '23 Feb 2021 07:34:11'	System	23 Feb 2021 13:34:14

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-28T08:56:11', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '32b23b2a-089b-47f2-a2ac-42e9d055a7f5' User entered 'No (N)'	System	28 Feb 2021 14:56:24
	System	28 Feb 2021 14:56:24

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-28T08:56:15', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '32b23b2a-089b-47f2-a2ac-42e9d055a7f5' User entered 'No (N)'	System	28 Feb 2021 14:56:24
	System	28 Feb 2021 14:56:24

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-28T08:56:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '32b23b2a-089b-47f2-a2ac-42e9d055a7f5' User entered '28 Feb 2021 08:56:21'	System	28 Feb 2021 14:56:24
	System	28 Feb 2021 14:56:24

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:08:51', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74'	System	18 Mar 2021 15:15:18
User entered 'Yes (Y)'	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:08:56', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74'	System	18 Mar 2021 15:15:18
User entered 'No (N)'	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:09:02', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74'	System	18 Mar 2021 15:15:18
User entered 'No (N)'	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:09:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74'	System	18 Mar 2021 15:15:18
User entered 'Yes (Y)'	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:09:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74'	System	18 Mar 2021 15:15:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-09T09:09:32', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd32e75f6-fd2e-4853-9cca-057059a91a74' User entered '09 Mar 2021 09:09:32'	System	18 Mar 2021 15:15:18
	System	18 Mar 2021 15:15:18

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:15:13', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876'	System	18 Mar 2021 15:16:16
User entered 'Yes (Y)'	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:15:17', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876'	System	18 Mar 2021 15:16:16
User entered 'No (N)'	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:15:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876'	System	18 Mar 2021 15:16:16
User entered 'No (N)'	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:15:32', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876'	System	18 Mar 2021 15:16:16
User entered 'Yes (Y)'	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:15:47', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876'	System	18 Mar 2021 15:16:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-03-18T10:16:07', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd98123e4-8a0b-41ad-9dc6-611293508876' User entered '18 Mar 2021 10:16:07'	System	18 Mar 2021 15:16:16
	System	18 Mar 2021 15:16:16

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-21T07:59:05', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8390e538-8446-4ed3-8416-04c21b315d15'	System	21 Mar 2021 12:59:27
User entered 'No (N)'	System	21 Mar 2021 12:59:27

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-21T07:59:12', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8390e538-8446-4ed3-8416-04c21b315d15'	System	21 Mar 2021 12:59:27
User entered 'No (N)'	System	21 Mar 2021 12:59:27

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-21T07:59:24', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '8390e538-8446-4ed3-8416-04c21b315d15'	System	21 Mar 2021 12:59:27
User entered '21 Mar 2021 07:59:24'	System	21 Mar 2021 12:59:27

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-30T12:59:11', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'cdd6168a-4e30-4d7f-90fb-e277d983159c' User entered 'No (N)'	System	30 Mar 2021 17:59:25
	System	30 Mar 2021 17:59:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-30T12:59:15', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'cdd6168a-4e30-4d7f-90fb-e277d983159c' User entered 'No (N)'	System	30 Mar 2021 17:59:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-03-30T12:59:21', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'cdd6168a-4e30-4d7f-90fb-e277d983159c' User entered '30 Mar 2021 12:59:21'	System	30 Mar 2021 17:59:25
	System	30 Mar 2021 17:59:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-07T18:04:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ae35057a-d704-48d4-98dc-1cb1b23070f0' User entered 'No (N)'	System	07 Apr 2021 23:05:57
	System	07 Apr 2021 23:05:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-07T18:04:31', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ae35057a-d704-48d4-98dc-1cb1b23070f0' User entered 'No (N)'	System	07 Apr 2021 23:05:57
	System	07 Apr 2021 23:05:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-07T18:04:36', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'ae35057a-d704-48d4-98dc-1cb1b23070f0' User entered '07 Apr 2021 18:04:36'	System	07 Apr 2021 23:05:57
	System	07 Apr 2021 23:05:57

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-13T12:01:06', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5ec1f64b-5c61-43f5-b71b-4092fa4459dd'	System	13 Apr 2021 17:10:25
User entered 'No (N)'	System	13 Apr 2021 17:10:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-13T12:08:19', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5ec1f64b-5c61-43f5-b71b-4092fa4459dd'	System	13 Apr 2021 17:10:25
User entered 'No (N)'	System	13 Apr 2021 17:10:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-13T12:08:27', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '5ec1f64b-5c61-43f5-b71b-4092fa4459dd' User entered '13 Apr 2021 12:08:27'	System	13 Apr 2021 17:10:25
	System	13 Apr 2021 17:10:25

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-20T12:00:39', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd0a07d08-6a6b-4d50-8b0e-4cdf78ee5a96'	System	20 Apr 2021 17:00:56
User entered 'No (N)'	System	20 Apr 2021 17:00:56

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-20T12:00:43', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd0a07d08-6a6b-4d50-8b0e-4cdf78ee5a96'	System	20 Apr 2021 17:00:56
User entered 'No (N)'	System	20 Apr 2021 17:00:56

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-04-20T12:00:52', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: 'd0a07d08-6a6b-4d50-8b0e-4cdf78ee5a96' User entered '20 Apr 2021 12:00:52'	System	20 Apr 2021 17:00:56
	System	20 Apr 2021 17:00:56

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-05-02T08:11:23', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '17715191-7210-4a39-a020-4e2a50525632'	System	02 May 2021 13:11:39
User entered 'No (N)'	System	02 May 2021 13:11:39

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-05-02T08:11:28', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '17715191-7210-4a39-a020-4e2a50525632'	System	02 May 2021 13:11:39
User entered 'No (N)'	System	02 May 2021 13:11:39

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EF44415-CB9F-483B-973C-E605CB1B672B)', Time: '2021-05-02T08:11:34', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '17715191-7210-4a39-a020-4e2a50525632'	System	02 May 2021 13:11:39
User entered '02 May 2021 08:11:34'	System	02 May 2021 13:11:39

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:27:38

US3232050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:27:38
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:27:38

US3232050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-28T08:56:31', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '77dc3f94-bcf8-4ece-9118-c2dc4d4baaa8'	System	28 Feb 2021 14:56:42
User entered 'No (N)'	System	28 Feb 2021 14:56:42

US3232050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:32:31
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6DB8CBCB-D7B4-46E8-B1BE-5B69C23F9D34)', Time: '2021-02-28T08:56:39', User OID: 'PatientReportedOutcome (US3232050)', ODM File OID: '77dc3f94-bcf8-4ece-9118-c2dc4d4baaa8'	System	28 Feb 2021 14:56:42
User entered '28 Feb 2021 08:56:39'	System	28 Feb 2021 14:56:42

US3232050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:36:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	10 Dec 2020 19:10:12
	(b) (4)	

US3232050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:36:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:23
	(b) (4), (b) (6)	
User entered '06 Nov 2020'	Jerrica Sullivan (b) (4)	10 Dec 2020 19:10:12
	(b) (4)	

US3232050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:36:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:23
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	10 Dec 2020 19:10:12
	(b) (4)	

US3232050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:36:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:40:23
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	10 Dec 2020 19:10:12

US3232050

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:36:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:40:15
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	10 Dec 2020 19:10:17
	(b) (4)	

US3232050

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:56:43
User entered 'I'	(b) (4), (b) (6) System	10 Dec 2020 19:10:17

US3232050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:03
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Yes (Y)'	Rambod Rouhbakhsh	10 Dec 2020 19:11:15
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:03
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered '10 Dec 2020'	Rambod Rouhbakhsh	10 Dec 2020 19:11:15
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:03
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Contact Made (CONTACT MADE)'	Rambod Rouhbakhsh	10 Dec 2020 19:11:15
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:03
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	10 Dec 2020 19:11:15
	(b) (4)	

US3232050

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:31
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Yes (Y)'	Rambod Rouhbakhsh	10 Dec 2020 19:11:19
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
User entered 'I'	(b) (4), (b) (6) System	10 Dec 2020 19:11:19

US3232050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:15:09
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 17:08:07
	(b) (4)	

US3232050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:15:09
	(b) (4), (b) (6)	
User entered '12 Jan 2021'	Jerrica Sullivan (b) (4)	12 Jan 2021 17:08:07
	(b) (4)	

US3232050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:15:09
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	12 Jan 2021 17:08:07
	(b) (4)	

US3232050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:15:09
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 17:08:07
	(b) (4)	

US3232050

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:15:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 17:08:12
	(b) (4)	

US3232050

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 17:08:12

US3232050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:45
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Yes (Y)'	Rambod Rouhbakhsh	12 Feb 2021 16:49:13
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:45
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Rambod Rouhbakhsh	25 Feb 2021 12:52:32
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm correct as entered, clinic closed due to inclement weather' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Jerrica Sullivan (b) (4)	23 Feb 2021 15:34:06
User entered '12 Feb 2021'	(b) (4)	
	System	12 Feb 2021 16:49:13
	Adreanna Pou (b) (4)	12 Feb 2021 16:49:13
	(b) (4)	

US3232050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:45
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Contact Made (CONTACT MADE)'	Rambod Rouhbakhsh	12 Feb 2021 16:49:13
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:45
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Feb 2021 16:49:13
	(b) (4)	

US3232050

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:48:52
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:40:08
User entered 'Yes (Y)'	Rambod Rouhbakhsh	08 Mar 2021 16:46:39
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:24:24
User entered 'I'	(b) (4), (b) (6) System	08 Mar 2021 16:46:39

US3232050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:04
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:41

US3232050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:04
	(b) (4), (b) (6)	
User entered '19 Mar 2021'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:48:41
	(b) (4)	

US3232050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:41

US3232050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered 'VISIT4'	(b) (4), (b) (6) System	30 Mar 2021 17:48:41

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:09
	(b) (4), (b) (6)	
User entered empty.	Jerrica Sullivan (b) (4)	30 Mar 2021 17:49:07
	(b) (4)	

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:09
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:49:07

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43

US3232050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43

US3232050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:17
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:47

US3232050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:17
User entered '19 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:47

US3232050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:22
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:59

US3232050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:22
	(b) (4), (b) (6)	
User entered '19 Mar 2021'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:48:59
	(b) (4)	

US3232050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:22
	(b) (4), (b) (6)	
User entered '12:03'	Jerrica Sullivan (b) (4)	30 Mar 2021 17:48:59
	(b) (4)	

US3232050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '19 Mar 2021 12:03'	(b) (4), (b) (6) System	30 Mar 2021 17:48:59

US3232050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 07:36:43
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:08:27
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:48:52

US3232050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:36:43
User entered '1'	(b) (4), (b) (6) System	30 Mar 2021 17:48:52

US3232050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:00:08
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Apr 2021 20:36:43
	(b) (4)	

US3232050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:00:08
	(b) (4)	
User entered '9 Apr 2021'	Adreanna Pou (b) (4)	09 Apr 2021 20:36:43
	(b) (4)	

US3232050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	09 Apr 2021 20:36:43
	(b) (4)	

US3232050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:00:08
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Apr 2021 20:36:43
	(b) (4)	

US3232050

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:00:08
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Apr 2021 20:40:49
	(b) (4)	

US3232050

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:42

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 20:40:49

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:23
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:31:27
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:23
	(b) (4), (b) (6)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:31:27
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:23
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:31:27
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	21 Jan 2021 19:31:27

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Mar 2021 21:54:42
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:39:39

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jerrica Sullivan (b) (4)	08 Mar 2021 21:54:42
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:39:39

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'mRNA-1273 (mRNA-1273)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'mRNA-1273 (mRNA-1273)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'mRNA-1273 (mRNA-1273)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:40
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:11
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
User entered empty.	(b) (4), (b) (6) System	21 Jan 2021 19:33:11

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:04:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
User entered empty.	(b) (4), (b) (6) System	21 Jan 2021 19:33:11

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:17
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:00
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:17
	(b) (4), (b) (6)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:00
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:17
	(b) (4), (b) (6)	
User entered '13:06'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:33:00
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
User entered '21 Jan 2021 13:06'	(b) (4), (b) (6) System	21 Jan 2021 19:33:00

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:22
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:32:50
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:22
	(b) (4), (b) (6)	
User entered '21 Jan 2021'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:32:50
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:22
	(b) (4), (b) (6)	
User entered '12:52'	Jerrica Sullivan (b) (4)	21 Jan 2021 19:32:50
	(b) (4)	

US3232050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:36
User entered '21 Jan 2021 12:52'	(b) (4), (b) (6) System	21 Jan 2021 19:32:50

US3232050

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:04:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:44
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:52
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:52:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	02 Mar 2021 20:05:26
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 12:20:33

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User coded data point as SOC: Gastrointestinal disorders, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Rambod Rouhbakhsh (b) (4) Coders Import (b) (4) (b) (4)	02 Mar 2021 20:07:52
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	02 Mar 2021 20:07:52
Data point term sent to Coders	System	02 Mar 2021 20:07:03
User entered 'diarrhea'	Jerrica Sullivan (b) (4) (b) (4)	02 Mar 2021 20:06:35

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '23 Sep 2020'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
User entered empty.	(b) (4), (b) (6) System	02 Mar 2021 20:06:35

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '24 Sep 2020'	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
User entered empty.	(b) (4), (b) (6) System	02 Mar 2021 20:06:35

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'None (NONE)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'l'	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Mar 2021 20:06:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
	Jerrica Sullivan (b) (4)	02 Mar 2021 20:06:35
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
User entered '0'	(b) (4), (b) (6) System	02 Mar 2021 20:06:35

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:33
User entered '0'	(b) (4), (b) (6) System	02 Mar 2021 20:06:35

US3232050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 12:20:33

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:30:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:30:55
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:47:43
User entered 'USA-US105-2021-mRNA-1273-P301000007'	System	08 Mar 2021 17:47:38
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 17:47:38

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 12:52:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:52:15
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM). Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 08:24:54
Data point term sent to Coder Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:36:59
Signature has been broken.	System Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:36:16 05 Apr 2021 15:36:00
User entered 'WORSENING SEVERE ACUTE CHRONIC SYMPTOMATIC ANEMIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:36:00
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 05:56:08
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User closed query 'PV Query: Please consider adding chronic anemia to medical history based on event of acute chronic symptomatic anemia. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:13:42

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider adding chronic anemia to medical history based on event of acute chronic symptomatic anemia. ' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:43:28
User closed query 'PV Query: The event term 'severe acute on chronic symptomatic anemia due to GI bleed' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 13:09:09
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Acute anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:10:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 14:10:33
User opened query 'PV Query: Please consider adding chronic anemia to medical history based on event of acute chronic symptomatic anemia. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 18:15:03
Data point term sent to Coder	System	15 Mar 2021 21:09:54
Query 'PV Query: The event term 'severe acute on chronic symptomatic anemia due to GI bleed' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:09:45
User entered 'SEVERE ACUTE CHRONIC SYMPTOMATIC ANEMIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:09:41
User opened query 'PV Query: The event term 'severe acute on chronic symptomatic anemia due to GI bleed' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:21:24
Query '(AE #2) PV Query: The event term 'severe acute on chronic symptomatic anemia due to GI bleed' contains multiple event terms. Please consider separating them into separate events.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:37

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
User opened query '(AE #2) PV Query: The event term "severe acute on chronic symptomatic anemia due to GI bleed" contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:18:05
Data point term sent to Coder	(b) (4), (b) (6)	
Coding entries removed.	System	05 Mar 2021 21:21:16
	Adreanna Pou (b) (4)	05 Mar 2021 21:20:16
	(b) (4)	
User entered 'severe acute on chronic symptomatic Anemia due to GI bleed' reason for change: Data Entry Error	Adreanna Pou (b) (4)	05 Mar 2021 21:20:16
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 20:50:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 20:50:15
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 20:49:44
User entered 'GI Bleed'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '04 Mar 2021'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:13:47
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:54:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:22:02
Query '(AE #2, #3) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:41
User opened query '(AE #2, #3) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:19:02
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:14:13
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	05 Mar 2021 20:50:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 20:49:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 20:49:41
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Mar 2021 20:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 20:49:13
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered '0' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:14:13
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 11:14:30
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:50:56
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Mar 2021 20:50:09
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	05 Mar 2021 20:50:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 20:50:09
User entered '1' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:50:09
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	05 Mar 2021 20:49:41
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 20:49:41

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	05 Mar 2021 20:49:41
User entered '0' reason for change: Data Entry Error	Adreanna Pou (b) (4)	05 Mar 2021 20:49:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) System	05 Mar 2021 20:49:13
User entered '1'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:14:13
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:13:50
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'done' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:07:19
User closed query 'Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 13:09:15
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 18:14:48
Query 'Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' answered with 'PATIENT WAS ADMITTED TO HOSPITAL ON 05MAR2021' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 20:56:16

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:23:30
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered '04 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:54:27
User entered '05 Mar 2021'	(b) (4)	
	Jerrica Sullivan (b) (4)	08 Mar 2021 16:50:42
	(b) (4)	
	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:14:13
	(b) (4)	
User entered '06 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:50:42
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:14:13
User closed query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 09:08:55
Query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 15:00:05
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 14:59:57
User opened query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 14:54:16
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 08:24:49
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'RED BLOOD CELLS ON CON MED LIST ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:37:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 13:53:07
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User entered 'I'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'updated procedures' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:51:17
	(b) (4), (b) (6)	
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'updated procedures' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 17:47:29
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:59:28
	(b) (4), (b) (6)	
User entered 'I'	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Mar 2021 16:04:00
User closed query 'Per CDM - RQ: Response noted. Please updated field to "Not Recovered/Not Resolved" or "Recovering/Resolving" from drop down list if AE is still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Mar 2021 09:03:22
Query 'Per CDM - RQ: Response noted. Please updated field to "Not Recovered/Not Resolved" or "Recovering/Resolving" from drop down list if AE is still ongoing. Please review and update accordingly. Else clarify.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:43:48
Query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:43:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:43:22
User opened query 'Per CDM - RQ: Response noted. Please updated field to "Not Recovered/Not Resolved" or "Recovering/Resolving" from drop down list if AE is still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 08:58:58
User closed query 'Per CDM: Please review and update the field from the available drop down list. Thank you ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 08:58:58
Query 'Per CDM: Please review and update the field from the available drop down list. Thank you ' answered with 'this condition is ongoing at this time' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 18:25:49

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please review and update the field from the available drop down list. Thank you ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:47:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:43:39
Query 'Data is required. Please complete.' answered with 'ongoing' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:54:33
User opened query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:22:45
Query '(AE #2, #3) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:46
User opened query '(AE #2, #3) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:19:50
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 20:49:13
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query: Did the subject have a medical history of portal hypertensive gastropathy/cirrhosis? Was the SAE considered a worsening of the subject's medical history of portal hypertensive gastropathy/cirrhosis?' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:14:08
User closed query 'PV Query: Please describe the source of GI bleed noted in the source document and consider whether this event meets criteria for SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:14:06
User closed query 'PV Query: Please confirm if hyperlipidemia, obstructive sleep apnea, colonoscopy, and diverticulosis are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If new findings, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:14:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:13:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 15:13:57
User closed query 'Per DM CLR: Narrative indicates that the subject had Colonoscopy. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:53:44

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had Colonoscopy. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'updated med history ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:54:26
Query 'PV Query: Did the subject have a medical history of portal hypertensive gastropathy/cirrhosis? Was the SAE considered a worsening of the subject's medical history of portal hypertensive gastropathy/cirrhosis?' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:52:02
Query 'PV Query: Please describe the source of GI bleed noted in the source document and consider whether this event meets criteria for SAE reporting. ' answered with 'esophageal varices and gastritis as well as ulcer are sources of gi bleed ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:48:25
Query 'PV Query: Please confirm if hyperlipidemia, obstructive sleep apnea, colonoscopy, and diverticulosis are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If new findings, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'added to med hx' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:08:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'completed' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:08:05
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 'not done ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:07:59
User closed query 'PV Query: Did the subject have a medical history of GI bleed?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 13:09:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

1898 of 2862

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had Colonoscopy. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 11:00:58
User opened query 'PV Query: Did the subject have a medical history of portal hypertensive gastropathy/cirrhosis? Was the SAE considered a worsening of the subject's medical history of portal hypertensive gastropathy/cirrhosis?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 18:15:39
User opened query 'PV Query: Please describe the source of GI bleed noted in the source document and consider whether this event meets criteria for SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 18:15:24
Query 'PV Query: Did the subject have a medical history of GI bleed?' answered with 'no medical history of GI bleed' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:09:00
User opened query 'PV Query: Please confirm if hyperlipidemia, obstructive sleep apnea, colonoscopy, and diverticulosis are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If new findings, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:23:14
User opened query 'PV Query: Did the subject have a medical history of GI bleed?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:22:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:22:19
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) (b) (4), (b) (6)	15 Mar 2021 16:21:39

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Query '(AE #2) PV Query: Please confirm if hyperlipidemia, obstructive sleep apnea, colonoscopy, and diverticulosis are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If new findings, please assess whether it meets criteria for separate AE/SAE reporting.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:57
Query '(AE #2) PV Query: Did the subject have a medical history of GI bleed?' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:55
Query '(AE #2) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:52
Query '(AE #2) 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.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:48
User opened query '(AE #2) PV Query: Please confirm if hyperlipidemia, obstructive sleep apnea, colonoscopy, and diverticulosis are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If new findings, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:20:10
User opened query '(AE #2) PV Query: Did the subject have a medical history of GI bleed?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:19:33
User opened query '(AE #2) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:19:20

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query '(AE #2) PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:18:37
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 units of PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED.' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:26:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 21:17:00
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 21:17:00

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User entered '73 y/o male w/hx of hypertension, Hyperlipidemia, Obstructive Sleep Apnea, Benign Prostatic Hypertrophy, Type 2 Diabetes Mellitus had an episode of dizziness, not feeling well some blurry vision, and shortness of breath. His blood pressure was low and he was transferred to ED. He reported black stool past couple of day. Also 2 episodes of hematemesis since last 2 days. He did not seek medical attention then until today he had a colonoscopy in 2018 which shows finding of diverticulosis. He presented to ED for persistent melena and symptoms of weakness. He was found to have hypotension and anemia with hemoglobin of 6.9. After treatment of PRBC and IV fluids his blood pressure and hemoglobin improved. Initial vitals: 74/34 improved to 120/60. Initial hemoglobin 6.9 improved to 9.9, lactic acid of 3.6. Hospitalized from ED with severe acute on chronic symptomatic Anemia due to GI bleed.' reason for change: Data Entry Error	Adreanna Pou (b) (4)	05 Mar 2021 21:17:00
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 20:49:41
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 19:14:13
User entered '1'	System	05 Mar 2021 20:49:41

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 20:49:13

US3232050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 14:59:57

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:25:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:25:23
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:11
User entered 'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	08 Mar 2021 17:48:08

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User coded data point as SOC: Gastrointestinal disorders, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Ulcer duodenal - version MedDRA\23.0.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 01:24:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 01:24:48
Data point term sent to Coder	System	05 Mar 2021 21:32:31
User entered 'ulcer of duodenum'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Yes (Y)'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '4 Mar 2021'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
User entered empty.	(b) (4), (b) (6) System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Rambod Rouhbakhsh	22 Mar 2021 17:55:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 17:55:56
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Jerrica Sullivan (b) (4)	22 Mar 2021 17:55:36
User entered 'Yes (Y)'	System	05 Mar 2021 21:32:25
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Rambod Rouhbakhsh	23 Mar 2021 15:14:32
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4)	
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 17:56:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Jerrica Sullivan (b) (4)	22 Mar 2021 17:55:36
User entered empty.	(b) (4)	15 Mar 2021 16:24:24
	(b) (4), (b) (6)	
	Adreanna Pou (b) (4)	05 Mar 2021 21:32:25
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
User entered empty.	(b) (4), (b) (6) System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:12:39
User entered 'Yes (Y)'	(b) (4)	05 Mar 2021 21:32:25
	Jerrica Sullivan (b) (4)	
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered '0' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:12:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 11:14:57
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:53:54
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 21:32:25
User entered '1'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:12:39
User closed query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4)	22 Mar 2021 13:09:34
Query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' answered with 'correct' (Site from Safety).	Jerrica Sullivan (b) (4)	19 Mar 2021 13:52:40
User opened query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:24:59
User entered '05 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 21:32:25
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:12:39
User entered '06 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:53:48
User entered empty.	(b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:12:39
User closed query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4)	12 Mar 2021 09:09:04
Query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4)	11 Mar 2021 15:00:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 15:00:25
User opened query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:54:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 21:32:53
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Admitted to ICU? is Yes, however	Rambod Rouhbakhsh	05 Mar 2021 21:32:53
Number of Days in ICU is missing. Please review	(b) (4)	
and reconcile.' (Site from System).		
Query 'Admitted to ICU? is Yes, however Number of System		05 Mar 2021 21:32:53
Days in ICU is missing. Please review and reconcile.'		
answered by data change (Site from System).		
User opened query 'Admitted to ICU? is Yes,	System	05 Mar 2021 21:32:25
however Number of Days in ICU is missing. Please		
review and reconcile.' (Site from System).		
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:32:25
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Data is required. Please complete.' (Site from System).	Rambod Rouhbakhsh	05 Mar 2021 21:33:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	05 Mar 2021 21:33:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	05 Mar 2021 21:33:55
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:32:25
User entered empty.	System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Data is required. Please complete.' (Site from System).	Rambod Rouhbakhsh	05 Mar 2021 21:33:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	05 Mar 2021 21:33:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	05 Mar 2021 21:33:55
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:32:25
User entered empty.	System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Data is required. Please complete.' (Site from System).	Rambod Rouhbakhsh	05 Mar 2021 21:33:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	05 Mar 2021 21:33:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	05 Mar 2021 21:32:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:32:25
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:26:09
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'PROTONIX ON CON MED LIST ' (Site from DM).	Jerrica Sullivan (b) (4)	05 Apr 2021 15:39:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:55:55
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered 'I'	(b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	Rambod Rouhbakhsh	24 Mar 2021 09:00:36
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'egd was utilized to correct ulcer' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 17:56:39
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	22 Mar 2021 11:02:34
	(b) (4), (b) (6)	
	Adreanna Pou (b) (4)	05 Mar 2021 21:32:25
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	Rambod Rouhbakhsh	23 Mar 2021 15:14:37
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'updated' (Site from Safety).	(b) (4)	22 Mar 2021 17:56:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 17:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 17:55:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	System	22 Mar 2021 17:55:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	Jerrica Sullivan (b) (4)	15 Mar 2021 16:24:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 21:32:25
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	05 Mar 2021 21:32:25
	(b) (4)	
	Adreanna Pou (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Rambod Rouhbakhsh	05 Mar 2021 21:33:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	(b) (4)	05 Mar 2021 21:33:55
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 UNITS OF PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED.' reason for change: Data Entry Error	System	05 Mar 2021 21:33:55
	Adreanna Pou (b) (4)	05 Mar 2021 21:33:55
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 21:32:25
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
	(b) (4), (b) (6)	
User entered '0'	System	23 Mar 2021 19:12:39
User entered '1'	System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
User entered 'I'	(b) (4), (b) (6) System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:45
	(b) (4), (b) (6)	
User entered '0'	System	11 Mar 2021 15:00:25
User entered '1'	System	05 Mar 2021 21:32:25

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:43
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	08 Mar 2021 17:48:40
'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Hypotension, LLT: Hypotension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 21:37:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 21:37:58
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 21:37:33
User entered 'hypotension'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '04 Mar 2021'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Mar 2021 16:55:06
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:55:06
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Mar 2021 21:36:40
User entered '13:27'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 16:55:06
User entered '04 Mar 2021 13:27'	System	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	10 Mar 2021 18:02:44
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 16:55:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 16:55:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:55:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:36:40
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '06 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	10 Mar 2021 18:02:44
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 11:15:13
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Mar 2021 21:36:40
User entered 'I'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered '04 Mar 2021' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	26 Mar 2021 20:53:11
User closed query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 13:09:44
Query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' answered with 'patient was admitted to hospital on 05mar2021' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:10:15
User opened query 'PV Query: Please confirm hospital admission date. Narrative and treatment medications indicate 04 Mar 2021. Was the subject given treatment in the ED on 04 Mar 2021 and then admitted on 05 Mar 2021?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:26:11
User entered '05 Mar 2021'	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '06 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 16:55:06
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM). Query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 09:09:14 11 Mar 2021 15:00:58
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 15:00:47
User opened query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and update accordingly. Else clarify.' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	11 Mar 2021 14:55:10 05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 17:50:10
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'UPDATED' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:42
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 16:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 16:55:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:33
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Mar 2021 22:46:19
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:36:40
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Mar 2021 17:50:11
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'UPDATED' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:46
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 16:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 16:55:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:33
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Mar 2021 22:46:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:36:40
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 13:09:47
Query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:10:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:10:44
User opened query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:26:44
Query '(AE #4) PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:26:16
User opened query '(AE #4) PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Mar 2021 16:16:42
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 16:55:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 16:55:33
User entered 'None (NONE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 16:55:33
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:36:40
User entered empty.	Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	19 Mar 2021 19:43:24
	(b) (4)	
User entered '1'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	19 Mar 2021 19:43:24
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:02:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 18:02:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jerrica Sullivan (b) (4)	10 Mar 2021 18:02:44
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 21:36:40
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Mar 2021 21:36:40
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 UNITS OF PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED.'	(b) (4) Adreanna Pou (b) (4) (b) (4)	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 21:36:40

US3232050

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 15:00:47

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:24:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:24:45
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	15 Mar 2021 17:31:24

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Gastric and oesophageal haemorrhages, PT: Portal hypertensive gastropathy, LLT: Portal hypertensive gastropathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:03:53
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:15:50
Data point term sent to Coder	System	06 Apr 2021 13:46:40
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately into separate logline to capture coding for all terms. Example: 1) WORSENING PORTAL HYPERTENSIVE 2) GASTROPATHY' (Site from System).	System	06 Apr 2021 13:46:31
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately into separate logline to capture coding for all terms. Example: 1) WORSENING PORTAL HYPERTENSIVE 2) GASTROPATHY' answered with 'this is one clinical diagnosis and cannot be split ' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	06 Apr 2021 13:46:31
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately into separate logline to capture coding for all terms. Example: 1) WORSENING PORTAL HYPERTENSIVE 2) GASTROPATHY' (Site from System).	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:53:43
Data point term sent to Coder	System	05 Apr 2021 15:40:21

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'UPDATED' (Site from DM). Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:40:12
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:40:07
User entered 'WORSENING PORTAL HYPERTENSIVE GASTROPATHY' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:40:07
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 05:57:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal haemorrhages, NEC, HLT: Gastric and oesophageal haemorrhages, PT: Portal hypertensive gastropathy, LLT: Portal hypertensive gastropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:42:45
Data point term sent to Coder	System	12 Mar 2021 13:42:22
User entered 'portal hypertensive gastropathy'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:09
	(b) (4)	
DataPoint Un-verified.	Jerrica Sullivan (b) (4)	26 Apr 2021 13:36:31
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	26 Apr 2021 13:36:31
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	26 Apr 2021 13:36:31
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:47:52
Query 'Per MM: please confirm seriousness assessment. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Apr 2021 13:36:48
User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 00:11:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Mar 2021 19:10:18
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Mar 2021 19:08:51
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:08:51
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 13:43:38
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 13:41:59
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User entered '0' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	23 Mar 2021 19:10:18
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) System	12 Mar 2021 13:43:38
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Mar 2021 13:43:38
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:43:38
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	12 Mar 2021 13:41:59
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:10:18
	(b) (4)	
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:10:18
	(b) (4)	
User entered '06 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:10:18
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 09:01:07
Query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:11:19
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:08:51
User opened query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 11:03:15
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:08:51
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:45:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 14:45:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jerrica Sullivan (b) (4)	24 Mar 2021 14:45:18
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 13:41:59
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 13:43:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Mar 2021 13:43:38
User entered 'chronic condition' reason for change:	Jerrica Sullivan (b) (4)	12 Mar 2021 13:43:38
Data Entry Error	(b) (4)	
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 13:41:59
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:41:59
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 19:08:51
User entered '1'	System	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 13:41:59

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:29:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:29:16
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 15:14:14
User entered 'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	15 Mar 2021 17:33:31

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Hepatic cirrhosis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 11:00:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:00:16
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:18:00
Data point term sent to Coder	System	06 Apr 2021 13:48:42
User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. WORSENING HEPATIC CIRRHOSIS Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	06 Apr 2021 13:48:09
Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. WORSENING HEPATIC CIRRHOSIS Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	06 Apr 2021 13:48:09
User entered 'WORSENING Hepatic CIRRHOSIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	06 Apr 2021 13:47:43
User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. WORSENING HEPATIC CIRRHOSIS Or Something else and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:01:43

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'updated' (Site from DM). Data point term sent to Coder Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:44:33
	System	05 Apr 2021 15:44:33
	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:44:28
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:44:28
User entered 'worsening CIRRHOSIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:44:28
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 05:57:57
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User coded data point as SOC: Hepatobiliary disorders, HLT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis liver - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:43:44
Data point term sent to Coder	System	12 Mar 2021 13:43:23
User entered 'cirrhosis'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:09
	(b) (4)	
DataPoint Un-verified.	Jerrica Sullivan (b) (4)	26 Apr 2021 13:37:21
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	26 Apr 2021 13:37:21
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	26 Apr 2021 13:37:21
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:47:58
Query 'Per MM: please confirm seriousness assessment. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Apr 2021 13:37:37
User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 00:11:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Mar 2021 19:15:49
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	23 Mar 2021 19:15:18
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:15:18
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Mar 2021 13:43:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:43:14
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	12 Mar 2021 13:43:01
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	23 Mar 2021 19:15:49
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).	System	23 Mar 2021 19:15:49
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:15:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) System	23 Mar 2021 19:15:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Mar 2021 13:43:01
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Mar 2021 13:43:01
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 13:43:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	12 Mar 2021 13:42:34
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:15:18
	(b) (4)	
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:15:18
	(b) (4)	
User entered '06 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:15:18
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 09:02:34
Query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:16:08
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	23 Mar 2021 19:15:18
User opened query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 11:03:28
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:15:18
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:45:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 14:45:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jerrica Sullivan (b) (4)	24 Mar 2021 14:45:54
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 13:42:34
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'chronic condition' reason for change:	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:52
Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:42:34
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 19:15:18
User entered '1'	System	12 Mar 2021 13:43:14
User entered '0'	System	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 13:42:34

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
Un-reviewed for Safety.	Rambod Rouhbakhsh	24 Mar 2021 14:27:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:27:04
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 15:14:14
User entered 'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	15 Mar 2021 17:32:06

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal vascular conditions, HLT: Oesophageal varices, PT: Varices oesophageal, LLT: Esophageal varices - version MedDRA\\23.0.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 13:45:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:45:44
Data point term sent to Coder	System	12 Mar 2021 13:45:24
User entered 'esophageal varices'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Yes (Y)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '05 Mar 2021'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '06 Mar 2021'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered 'Yes (Y)'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered '1'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered '05 Mar 2021'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered '06 Mar 2021'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered 'No (N)'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Applicable (NOT APPLICABLE)'	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan	
	(b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	Rambod Rouhbakhsh	24 Mar 2021 09:03:13
Query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' answered with 'updated' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:18:05
User opened query 'Per DM CLR: Please review this SAE and please note, there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment was given.' (Site from DM).	(b) (4)	23 Mar 2021 19:17:56
User entered '1'	(b) (4), (b) (6)	22 Mar 2021 11:03:42
	(b) (4), (b) (6)	
	Jerrica Sullivan (b) (4)	12 Mar 2021 13:44:55
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '1' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered '0'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '1' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:17:56
User entered '0'	(b) (4)	12 Mar 2021 13:44:55
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Data is required. Please complete.' (Site from System).	Rambod Rouhbakhsh	12 Mar 2021 13:46:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	12 Mar 2021 13:46:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	12 Mar 2021 13:46:45
Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 13:44:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 13:44:55
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:44:55
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:44:55
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Rambod Rouhbakhsh	12 Mar 2021 13:51:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	(b) (4)	System
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 UNITS OF PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 13:51:08

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 13:44:55
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
	(b) (4), (b) (6)	
User entered '0'	System	23 Mar 2021 19:17:56
User entered '1'	System	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
User entered '1'	(b) (4), (b) (6) System	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:20:57
User entered '0'	(b) (4), (b) (6) System	12 Mar 2021 13:44:55

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:22
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
Un-reviewed for Safety.	Rambod Rouhbakhsh	24 Mar 2021 14:27:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 14:27:33
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 15:14:14
User entered 'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	15 Mar 2021 17:32:38

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Rambod Rouhbakhsh	12 Mar 2021 13:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Mar 2021 13:46:44
Data point term sent to Coder	Coder Import (b) (4)	12 Mar 2021 13:46:25
User entered 'gastritis'	System	12 Mar 2021 13:46:23
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Yes (Y)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '05 Mar 2021'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '06 Mar 2021'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'No (N)' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:20:54
User entered 'Yes (Y)'	(b) (4)	12 Mar 2021 13:46:23
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0' reason for change: Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:20:54
User entered '1'	(b) (4)	12 Mar 2021 13:46:23
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:20:54
User entered '05 Mar 2021'	(b) (4)	12 Mar 2021 13:46:23
	Jerrica Sullivan (b) (4)	
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty; reason for change Data Entry Error	Rambod Rouhbakhsh	23 Mar 2021 19:20:54
User entered '06 Mar 2021'	(b) (4)	12 Mar 2021 13:46:23
	Jerrica Sullivan (b) (4)	
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	23 Mar 2021 19:20:54
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:46:23
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Related (NOT RELATED)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Not Applicable (NOT APPLICABLE)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '0'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Per CDM: Please verify that Concomitant Medication check box is not selected, however there's corresponding CM # 18 recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	Rambod Rouhbakhsh	24 Mar 2021 09:05:03
Query 'Per CDM: Please verify that Concomitant Medication check box is not selected, however there's corresponding CM # 18 recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	23 Mar 2021 19:21:00
User entered '1' reason for change: Data Entry Error	(b) (4)	23 Mar 2021 19:20:54
User opened query 'Per CDM: Please verify that Concomitant Medication check box is not selected, however there's corresponding CM # 18 recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:48:52
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	Rambod Rouhbakhsh	24 Mar 2021 09:05:01
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' answered with 'procedure was utilized both diagnostic and therapeutic ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 17:58:05
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure record was noted as a Diagnostic procedure rather than therapeutic. Please review and update to record the treatment procedure for this AE as applicable. Otherwise, clarify.' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 11:04:04
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	12 Mar 2021 13:46:23
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Rambod Rouhbakhsh	12 Mar 2021 13:51:25
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	(b) (4)	System
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 UNITS OF PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 13:51:25

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 13:46:23
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
	(b) (4), (b) (6)	
User entered '0'	System	23 Mar 2021 19:20:54
User entered '1'	System	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
User entered '1'	(b) (4), (b) (6) System	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:21:03
User entered '0'	(b) (4), (b) (6) System	12 Mar 2021 13:46:23

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 15:16:27
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	23 Mar 2021 15:15:36
'USA-US105-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: Gastrointestinal bleed - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:18:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 21:18:45
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 21:18:03
User entered 'Gastrointestinal bleed'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 17:58:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '05 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 17:58:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	15 Mar 2021 21:20:29
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	15 Mar 2021 21:17:45
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
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)	15 Mar 2021 21:20:29
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	15 Mar 2021 21:20:29
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:20:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 21:17:45
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'PV Query: Please confirm hospital admission date. Narrative states subject was admitted on 05 Mar 2021; discharge summary states subject was admitted on 04 Mar 2021' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:23:17
Query 'PV Query: Please confirm hospital admission date. Narrative states subject was admitted on 05 Mar 2021; discharge summary states subject was admitted on 04 Mar 2021' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 20:52:12
User entered '04 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 20:51:30
User opened query 'PV Query: Please confirm hospital admission date. Narrative states subject was admitted on 05 Mar 2021; discharge summary states subject was admitted on 04 Mar 2021' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 12:47:06
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '06 Mar 2021'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:17:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 21:17:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:17:45
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:17:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 21:17:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:17:45
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:48:08
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 15:48:08
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	15 Mar 2021 21:18:16
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there are Con Meds recorded that match this AE during this timeframe (CM#s 6-10). Please review if 'Concomitant Medication' should also be checked/ticked. Otherwise, please clarify.' (Site from DM). Query 'Per DM CLR: Treatment Required = Con Procedure, however there are Con Meds recorded that match this AE during this timeframe (CM#s 6-10). Please review if 'Concomitant Medication' should also be checked/ticked. Otherwise, please clarify.' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there are Con Meds recorded that match this AE during this timeframe (CM#s 6-10). Please review if 'Concomitant Medication' should also be checked/ticked. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 08:28:42
User signature succeeded.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:48:15
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Apr 2021 13:58:36
	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 13:38:57
	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 17:58:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 17:58:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jerrica Sullivan (b) (4)	22 Mar 2021 17:58:58
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:17:45
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	15 Mar 2021 21:17:45
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 13:38:57
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 21:20:57
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 21:20:57
User entered '73 Y/O MALE W/HX OF HYPERTENSION, HYPERLIPIDEMIA, OBSTRUCTIVE SLEEP APNEA, BENIGN PROSTATIC HYPERTROPHY, TYPE 2 DIABETES MELLITUS HAD AN EPISODE OF DIZZINESS, NOT FEELING WELL SOME BLURRY VISION, AND SHORTNESS OF BREATH. HIS BLOOD PRESSURE WAS LOW AND HE WAS TRANSFERRED TO ED. HE REPORTED BLACK STOOL PAST COUPLE OF DAY. ALSO 2 EPISODES OF HEMATEMESIS SINCE LAST 2 DAYS. HE DID NOT SEEK MEDICAL ATTENTION THEN UNTIL TODAY HE HAD A COLONOSCOPY IN 2018 WHICH SHOWS FINDING OF DIVERTICULOSIS. HE PRESENTED TO ED FOR PERSISTENT MELENA AND SYMPTOMS OF WEAKNESS. HE WAS FOUND TO HAVE HYPOTENSION AND ANEMIA WITH HEMOGLOBIN OF 6.9. AFTER TREATMENT OF 3 UNITS OF PRBC AND IV FLUIDS HIS BLOOD PRESSURE AND HEMOGLOBIN IMPROVED. INITIAL VITALS: 74/34 IMPROVED TO 120/60. INITIAL HEMOGLOBIN 6.9 IMPROVED TO 9.9, LACTIC ACID OF 3.6. HOSPITALIZED FROM ED WITH SEVERE ACUTE ON CHRONIC SYMPTOMATIC ANEMIA DUE TO GI BLEED' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:20:57
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 21:17:45

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 10:01:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 10:01:56
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 19:28:57
User entered 'worsening mixed hyperlipidemia'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:28:01

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:28:01

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:51:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 19:28:01
	(b) (4)	

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:28:01

US3232050

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:04:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:28:01

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:44
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:22:09
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:53
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Nov 2020 13:27:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 13:27:37
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	09 Nov 2020 13:27:23 09 Nov 2020 13:27:23
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.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 18:56:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:56:20
Data point term sent to Coder User entered 'Tamsulosin'	System Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:54:42 14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Also, ensure that updated indication is recorded in the Medical History eCRF, if needed. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 21:35:04
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Also, ensure that updated indication is recorded in the Medical History eCRF, if needed. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:27
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:23
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Also, ensure that updated indication is recorded in the Medical History eCRF, if needed. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:36:57
User entered 'prostate'	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review the dose of this medication 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) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 21:35:08
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:30
User entered '0.4' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:23
User opened query 'Per DM CLR: Please review the dose of this medication 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) (b) (4), (b) (6)	14 Sep 2020 13:37:14
User entered '04'	Jerrica Sullivan (b) (4) (b) (4)	14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '10 Aug 2020'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 18:53:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 18:53:51
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 18:53:44
User entered empty.	Jerrica Sullivan (b) (4)	14 Aug 2020 18:53:44
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 18:53:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 15:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:13:36
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	09 Nov 2020 13:28:24 09 Nov 2020 13:27:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Aug 2020 21:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:22:45
Data point term sent to Coder User entered 'aspirin'	System Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:47:12 24 Aug 2020 15:47:11

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 21:28:23
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:44
User entered 'CARDIAC PROHYLACTIC' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:40
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 10:25:39
User entered 'prohylactic'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:47:11

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '81'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'un UNK 2010'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:11
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:47:11

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:47:11

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:47:11

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 13:29:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 13:29:31
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	09 Nov 2020 13:28:24
	Jerrica Sullivan (b) (4)	09 Nov 2020 13:27:56
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:49:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:49:07
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:48:13
User entered 'lisinopril'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 21:37:11
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:28:00
User entered 'HYPERTENSION' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Nov 2020 13:27:56
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 13:38:13
User entered 'blood pressure'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:47:41

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '16 Apr 2020'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:47:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:47:52
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:47:41
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:47:41
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:47:41

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:47:41

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:47:41

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN;SITAGLIPTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 09:31:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:31:51
Data point term sent to Coder	System	24 Aug 2020 15:49:14
User entered 'sitagliptine metformin'	Jerrica Sullivan (b) (4) (b) (4)	24 Aug 2020 15:48:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'diabetes'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '50-1000'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '16 Apr 2020'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:48:36
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 15:48:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:48:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:48:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:50:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 15:50:37
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 15:50:15
User entered 'glimepiride'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'diabetes'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '2'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '16 Apr 2020'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Aug 2020 15:49:20
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:49:20

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:49:20

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:49:20

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: HYPOTHALAMIC HORMONES, ATC: SOMATOSTATIN AND ANALOGUES, PRODUCT: OCTREOTIDE ACETATE, PRODUCTSYNONYM: SANDOSTATIN - version WHODrug-Global-B3\202003.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 13:54:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:54:50
Data point term sent to Coder	System	12 Mar 2021 13:53:35
User entered 'sandostatin'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'upper gastrointestinal bleed'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '50'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'ug (ug)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'once (ONCE)'	Jerrica Sullivan	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:54:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:54:51
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:05

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 11:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Apr 2021 11:22:49
Data point term sent to Coder	System	05 Apr 2021 15:39:19
Coding entries removed.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:39:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:41:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Mar 2021 09:41:31
Data point term sent to Coder	System	12 Mar 2021 13:54:35
User entered 'protonix'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User entered 'UPPER GASTROINTESTINAL BLEED/ULCER OF DUODENUM' reason for change: Data Entry Error	Rambod Rouhbakhsh	05 Apr 2021 15:39:11
User entered 'upper gastrointestinal bleed'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '80'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User entered 'once (ONCE)' reason for change: Data Entry Error	Rambod Rouhbakhsh	12 Mar 2021 14:07:37
User entered 'other (OTHER)'	(b) (4)	12 Mar 2021 13:53:39
	Jerrica Sullivan	
	(b) (4)	
	Jerrica Sullivan	
	(b) (4)	
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Mar 2021 14:07:37
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	12 Mar 2021 13:53:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:00
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:53:39

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: HYPOTHALAMIC HORMONES, ATC: SOMATOSTATIN AND ANALOGUES, PRODUCT: OCTREOTIDE ACETATE, PRODUCTSYNONYM: SANDOSTATIN - version WHODrug-Global-B3\\202003.	(b) (4)	12 Mar 2021 13:56:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 13:56:45
Data point term sent to Coder	System	12 Mar 2021 13:55:36
User entered 'sandostatin'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'upper gastrointestinal bleed'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '600'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'ug (ug)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'other (OTHER)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'continuous infusion daily'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:20
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:54:55

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import	06 Apr 2021 11:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	06 Apr 2021 11:22:49
Data point term sent to Coder	System	05 Apr 2021 15:40:20
Coding entries removed.	Jerrica Sullivan	05 Apr 2021 15:39:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 09:41:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 09:41:31
Data point term sent to Coder	System	12 Mar 2021 13:56:36
User entered 'protonix'	Jerrica Sullivan	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User entered 'UPPER GASTROINTESTINAL BLEED/ULCER OF DUODENUM' reason for change: Data Entry Error	Rambod Rouhbakhsh	05 Apr 2021 15:39:28
User entered 'upper gastrointestinal bleed'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '1920'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'continuous infusion daily'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:26
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:56:34

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
User closed query 'Per MM: Per protocol section 6.4.3, the administration of any blood products is prohibited (except for treatment of COVID-19). Please ensure a protocol deviation has been completed. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 11:55:39
Query 'Per MM: Per protocol section 6.4.3, the administration of any blood products is prohibited (except for treatment of COVID-19). Please ensure a protocol deviation has been completed. ' answered with 'deviation noted ' (Site from DM).	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 17:46:46 12 Apr 2021 13:07:26
User opened query 'Per MM: Per protocol section 6.4.3, the administration of any blood products is prohibited (except for treatment of COVID-19). Please ensure a protocol deviation has been completed. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 12:43:38
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:41:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:10:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:10:38
Data point term sent to Coder	System	05 Apr 2021 15:38:18

PRODUCTION RELEASE (v12.003
EAB) (1725)

2361 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:38:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 09:47:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:47:40
Data point term sent to Coder	System	12 Mar 2021 13:57:37
User entered 'packed red blood cells'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User entered 'UPPER GASTROINTESTINAL BLEED/WORSENING SEVERE ACUTE CHRONIC SYMPTOMATIC ANEMIA/ESOPHAGEAL VARICES' reason for change: Data Entry Error	Rambod Rouhbakhsh	05 Apr 2021 15:38:05
User entered 'upper gastrointestinal bleed'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '3'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'units'	Jerrica Sullivan	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'stat daily'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:57:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 16:03:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:03:35
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 12:09:49
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'AE log updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	06 Apr 2021 12:51:34
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:57:46 05 Apr 2021 15:57:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:26:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:26:24

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 11:16:17
Data point term sent to Coder	System	22 Mar 2021 18:00:07
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:59:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:59:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:59:44
Data point term sent to Coder	System	12 Mar 2021 13:58:38
User entered 'lovastatin'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:58:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'worsening MIXED HYPERLIPIDEMIA' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 15:57:42
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:32:05
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:59:35
User entered 'mixed hyperlipidemia' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 17:59:29
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:28:27
User entered 'elevated cholesterol'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:58:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:58:03
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 13:58:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 13:58:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 13:58:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 12:41:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 12:41:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 21:58:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 21:58:54
Data point term sent to Coder	System	12 Mar 2021 13:59:39
User entered '.9% sodium chloride'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 12:17:01
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	19 Mar 2021 19:42:53
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:30:38
User entered 'hypotension'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '1000'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mL (mL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'continuous daily'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:04
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 13:59:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Apr 2021 15:45:45
Data point term sent to Coder Coding entries removed.	Coder Import (b) (4)	05 Apr 2021 15:45:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4)	05 Apr 2021 15:34:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:33:26
Data point term sent to Coder Coding entries removed.	(b) (4)	22 Mar 2021 18:00:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 18:00:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	22 Mar 2021 18:00:09
Data point term sent to Coder Coding entries removed.	System	22 Mar 2021 18:00:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Jerrica Sullivan (b) (4)	22 Mar 2021 18:00:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Mar 2021 14:01:45
Data point term sent to Coder Coding entries removed.	Coder Import (b) (4)	12 Mar 2021 14:01:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4)	12 Mar 2021 14:01:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 14:01:45
Data point term sent to Coder Coding entries removed.	(b) (4)	12 Mar 2021 14:00:44
User entered 'acetaminophen'	System	12 Mar 2021 14:00:03
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	Rambod Rouhbakhsh	06 Apr 2021 09:50:10
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	Jerrica Sullivan (b) (4)	05 Apr 2021 15:33:37
' answered with 'CORRESPONDS WITH GI BLEED' (Site from DM).	(b) (4)	
User entered 'PAIN (STOMACH) SECONDARY TO GI BLEED' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 15:33:26
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	29 Mar 2021 11:12:30
' (Site from DM).	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate.	(b) (4), (b) (6)	23 Mar 2021 11:34:16
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate.	Jerrica Sullivan (b) (4)	22 Mar 2021 18:00:12
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'PAIN (stomach)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:00:08
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:46:58
User entered 'pain'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '500'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import	30 Mar 2021 14:03:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	30 Mar 2021 14:03:20
Data point term sent to Coder	System	22 Mar 2021 18:01:10
Coding entries removed.	Jerrica Sullivan	22 Mar 2021 18:00:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import	15 Mar 2021 07:17:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	15 Mar 2021 07:17:19
Data point term sent to Coder	System	12 Mar 2021 14:00:55
User entered 'fentanyl'	Jerrica Sullivan	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Indication=Pain, Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	Rambod Rouhbakhsh	23 Mar 2021 11:36:34
User closed query 'Per DM CLR: Indication=Anesthesia, Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:36:29
Query 'Per DM CLR: Indication=Pain, Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:01:06
Query 'Per DM CLR: Indication=Anesthesia, Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:01:00
User entered 'PAIN(stomach) /ANESTHESIA (EGD)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:00:54
User opened query 'Per DM CLR: Indication=Pain, Please update the indication to reflect the location and type of Pain. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:50:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication=Anesthesia, Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:49:07
User entered 'pain/anesthesia'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '20/50'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'ug (ug)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:12
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:00:44

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: FLUMAZENIL - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	30 Mar 2021 14:03:39
Data point term sent to Coder	Coder Import (b) (4)	30 Mar 2021 14:03:39
Data point term sent to Coder	(b) (4)	30 Mar 2021 14:03:39
Coding entries removed.	System	24 Mar 2021 13:22:02
	System	22 Mar 2021 18:02:11
	Jerrica Sullivan (b) (4)	22 Mar 2021 18:01:35
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: FLUMAZENIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 01:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	15 Mar 2021 01:37:47
Data point term sent to Coder	Coder Import (b) (4)	15 Mar 2021 01:37:47
Data point term sent to Coder	(b) (4)	15 Mar 2021 01:37:47
User entered 'flumazenil'	System	12 Mar 2021 14:08:13
	System	12 Mar 2021 14:01:55
	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:01:35
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' (Site from DM).	Rambod Rouhbakhsh	29 Mar 2021 10:14:05
Query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	24 Mar 2021 13:21:23
User entered 'PREVENTIVE of anesthesia OVERDOSE' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 13:21:09
User opened query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:32:14
User closed query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:30:12
Query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' answered with 'this is for prevention of anesthesia overdose, no underlying medical condition to note' (Site from DM).	Jerrica Sullivan (b) (4)	23 Mar 2021 13:37:01
User opened query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:38:26

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:38:26
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:01:41
User entered 'preventive OVERDOSE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:01:35
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:44:11
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 14:08:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 14:08:05
User entered 'overdose' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:08:05
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 14:01:27
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '.4'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'mg (mg)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:01:27

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:03:31
Data point term sent to Coder	System	22 Mar 2021 18:02:11
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:01:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 10:22:49
Data point term sent to Coder	System	12 Mar 2021 14:02:58
User entered 'versed'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate' (Site from DM).	Rambod Rouhbakhsh	23 Mar 2021 11:39:39
User closed query 'Per DM CLR: Please review corresponding AE if ESOPHAGEAL VARICES as this does not indicate "Other Action Taken = Concomitant Medication" "Concomitant Procedure", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:39:36
Query 'Per DM CLR: Please review corresponding AE if ESOPHAGEAL VARICES as this does not indicate "Other Action Taken = Concomitant Medication" "Concomitant Procedure", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated to indicated egd' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:02:51
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:02:04
User entered 'ANESTHESIA (EGD)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 18:01:53

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review corresponding AE if ESOPHAGEAL VARICES as this does not indicate "Other Action Taken = Concomitant Medication" "Concomitant Procedure", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:26:25
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:23:33
User entered 'anesthesia'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '1-2'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:03

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import	25 Mar 2021 04:32:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	25 Mar 2021 04:32:47
Data point term sent to Coder	System	24 Mar 2021 13:22:02
Coding entries removed.	Jerrica Sullivan	24 Mar 2021 13:22:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 05:27:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 05:27:28
Data point term sent to Coder	System	22 Mar 2021 18:03:12
Coding entries removed.	Jerrica Sullivan	22 Mar 2021 18:03:06
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003.	Coder Import	17 Mar 2021 13:39:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	17 Mar 2021 13:39:42
Data point term sent to Coder	System	12 Mar 2021 14:02:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

2493 of 2862

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Narcan'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:03:06
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' (Site from DM).	Rambod Rouhbakhsh	29 Mar 2021 10:13:44
Query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	24 Mar 2021 13:22:13
User entered 'PREVENTIVE of anesthesia OVERDOSE' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 13:22:00
User opened query 'Per CDM: Please consider to update the 'indication' as per your previous response 'prevention of anesthesia overdose' else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:31:59
User closed query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:31:59
Query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' answered with 'this is for prevention of anesthesia overdose, no underlying medical condition to note' (Site from DM).	Jerrica Sullivan (b) (4)	23 Mar 2021 13:37:52
User opened query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:40:24

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 11:40:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:03:16
User entered 'preventive OVERDOSE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:03:06
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:44:24
User entered 'overdose'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '.4'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:49
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:02:36

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 06:42:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	24 Mar 2021 06:42:28
Data point term sent to Coder	System	22 Mar 2021 18:04:14
Coding entries removed.	Jerrica Sullivan	22 Mar 2021 18:03:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import	12 Mar 2021 14:04:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import	12 Mar 2021 14:04:44
Data point term sent to Coder	System	12 Mar 2021 14:04:08
User entered 'ondansetron'	Jerrica Sullivan	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:40:49
Query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:03:59
User entered 'NAUSEA (gastritis)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:03:51
User opened query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:40:27
User entered 'nausea'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '4'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	Rambod Rouhbakhsh	12 Mar 2021 14:08:33
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	(b) (4)	12 Mar 2021 14:08:33
User entered 'other (OTHER)' reason for change:	System	12 Mar 2021 14:08:33
Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	12 Mar 2021 14:03:16
User entered 'once (ONCE)'	System	12 Mar 2021 14:03:16
	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered 'once as needed' reason for change:	Jerrica Sullivan (b) (4)	12 Mar 2021 14:08:33
Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:56:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:56
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:16

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import	25 Mar 2021 09:01:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import	25 Mar 2021 09:01:01
Data point term sent to Coder	System	22 Mar 2021 18:05:17
Data point term sent to Coder	System	12 Mar 2021 14:04:08
User entered 'promethazine'	Jerrica Sullivan	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' (Site from DM).	(b) (4)	23 Mar 2021 11:49:25
Query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:04:25
User entered 'NAUSEA (gastritis)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 18:04:18
User opened query 'Per DM CLR: Please note, there are AEs (e.g., Gastritis, Esophageal Varices, Ulcer of Duodenum, etc.) reported within the same time frame that matches this Con Med indication. Please confirm the underlying medical condition for this Con Med use. Otherwise, add a medical condition NAUSEA and update all applicable details to the appropriate AE eCRF. As well as, ensure to indicate "Other Action Taken=Concomitant Medication". ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:42:22
User entered 'nausea'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '12.5'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:01
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:03:45

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh	25 Mar 2021 08:59:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:59:04
Data point term sent to Coder	System	12 Mar 2021 14:05:10
User entered 'Propofol'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'esophagogastroduodenoscopy'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '300'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:07
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:04:48

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 10:03:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 10:03:29
Data point term sent to Coder	System	22 Mar 2021 18:05:17
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:04:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:17:58
Data point term sent to Coder	System	12 Mar 2021 14:09:15
User entered 'SODIUM CHLORIDE .9% flush' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:08:51
Data point term sent to Coder	System	12 Mar 2021 14:06:11
User entered 'sodium chloride'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:04:59
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify. ' (Site from DM).	Rambod Rouhbakhsh	24 Mar 2021 10:32:44
Query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify. ' answered with 'no underlying medical condition to note, this is to prevent infection and clear iv line ' (Site from DM).	Jerrica Sullivan (b) (4)	23 Mar 2021 13:39:39
User opened query 'Per CDM: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:50:15
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:50:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	22 Mar 2021 18:05:08
User entered 'PERIPHERAL IV FLUSH (preventive)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:04:59

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 16:51:29
User entered 'peripheral IV flush'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '10'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mL (mL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'every 8 hours'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '04 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '06 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:32
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:05:32

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 13:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:31:42
Data point term sent to Coder	System	12 Mar 2021 14:07:12
User entered 'lidocaine 2%'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'esophagogastroduodenoscopy'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '100'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'once (ONCE)'	Jerrica Sullivan	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:38
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:06:18

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: BIGUANIDES AND AMIDINES, PRODUCT: CHLORHEXIDINE GLUCONATE, PRODUCTSYNONYM: HIBICLENS - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh (b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:39
Data point term sent to Coder	System	22 Mar 2021 18:06:31
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 18:05:24
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: BIGUANIDES AND AMIDINES, PRODUCT: CHLORHEXIDINE GLUCONATE, PRODUCTSYNONYM: HIBICLENS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:33:09
Data point term sent to Coder	System	12 Mar 2021 14:07:13
User entered 'hibiclens'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:21:58
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition or procedure that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.	Rambod Rouhbakhsh	23 Mar 2021 11:50:39
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition or procedure that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.	Jerrica Sullivan (b) (4)	22 Mar 2021 18:05:33
' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered 'PRE-OPERATIVE PROTOCOL (EGD)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Mar 2021 18:05:24
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition or procedure that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:53:15
User entered 'pre-operative protocol'	(b) (4), (b) (6)	
	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10
	(b) (4)	

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '4 % '	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'solution'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'once (ONCE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'Topical (TOPICAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '0'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered '05 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 08:57:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 17:46:46
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:43
User entered empty.	(b) (4), (b) (6) System	12 Mar 2021 14:07:10

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:04:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:44
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:28
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
DataPoint Un-verified.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:09:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	12 Mar 2021 14:09:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 17:22:22
	(b) (4), (b) (6)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Aug 2020 18:49:41
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered '05 Mar 2021'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:10:03
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'esophagogastroduodenoscopy'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:10:03
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered 'Adverse Event (AE)'	Jerrica Sullivan (b) (4)	12 Mar 2021 14:10:03
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:42

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:38:57
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	12 Mar 2021 14:10:03
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:46:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered '04 Mar 2021'	Rambod Rouhbakhsh	22 Mar 2021 17:46:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:46:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'blood transfusion (packed red blood cells)'	Rambod Rouhbakhsh	22 Mar 2021 17:46:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:46:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered 'Adverse Event (AE)'	Rambod Rouhbakhsh	22 Mar 2021 17:46:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:46:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:52:34
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 13:38:57
User entered empty.	Rambod Rouhbakhsh	22 Mar 2021 17:46:35
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Rambod'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Rambod'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '08/Mar/2021 12:48'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 17:49:05
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Rambod'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
User entered '09/Mar/2021 10:50'	(b) (4), (b) (6)	
	System	09 Mar 2021 15:50:24

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 15:50:24
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
User entered '11/Mar/2021 09:30'	(b) (4), (b) (6)	
	System	11 Mar 2021 14:30:09

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:30:13
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 14:30:09
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
User entered '12/Mar/2021 09:01'	(b) (4), (b) (6)	
	System	12 Mar 2021 14:01:12

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 17:34:29
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 14:01:12
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '15/Mar/2021 13:34'	System	15 Mar 2021 17:35:07

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:10:13
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 17:35:07
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
User entered '16/Mar/2021 10:06'	(b) (4), (b) (6)	
	System	16 Mar 2021 14:07:09

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:10:13
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 14:07:09
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Rambod'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '18/Mar/2021 11:51'	System	18 Mar 2021 15:51:59

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 13:10:22
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 15:51:59
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
User entered '22/Mar/2021 08:10'	(b) (4), (b) (6)	
	System	22 Mar 2021 13:11:01

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 15:16:56
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 13:11:01
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '23/Mar/2021 11:17'	System	23 Mar 2021 15:17:35

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:31:57
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 15:17:35
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Rouhbakhsh'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '24/Mar/2021 10:31'	System	24 Mar 2021 14:31:53

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:04:42

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.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:31:57
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 14:31:53
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered '29/Mar/2021 09:24'	System	29 Mar 2021 16:24:20

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:04:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:32:38
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 16:24:20
	(b) (4), (b) (6)	

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered	(b) (4), (b) (6)	
'USA-US105-2021-MRNA-1273-P301000007'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'No (N)'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rambod'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:53
	(b) (4), (b) (6)	
User entered 'Rouhbakhsh'	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'Petal'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered 'MS'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
Reviewed for Safety.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	08 Mar 2021 17:48:53
User entered '39465'	(b) (4), (b) (6)	
	System	08 Mar 2021 17:47:38

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 13:40:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 19:10:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 15:50:29
	(b) (4), (b) (6)	
User entered 'US'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	06 Apr 2021 13:32:59
User entered '11'	System	29 Mar 2021 16:24:20
User entered '10'	System	24 Mar 2021 14:31:53
User entered '9'	System	23 Mar 2021 15:17:35
User entered '8'	System	22 Mar 2021 13:11:01
User entered '7'	System	18 Mar 2021 15:51:59
User entered '6'	System	16 Mar 2021 14:07:09
User entered '5'	System	15 Mar 2021 17:35:07
User entered '4'	System	12 Mar 2021 14:01:12
User entered '3'	System	11 Mar 2021 14:30:09
User entered '2'	System	09 Mar 2021 15:50:24
User entered '1'	System	08 Mar 2021 17:49:05

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:04:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:13
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:21:58
	(b) (4)	
User entered '06/Apr/2021 08:32'	System	06 Apr 2021 13:32:59

US3232050

Folder: SAE USA-US105-2021-MRNA-1273-P301000007

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:04:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:50:13
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:21:58
User entered 'I'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:32:59