

US3552232 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:38

All time stamps listed in this document are displayed in GMT

US3552232

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:38

[Participant ID](#)

US3552232

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

US3552232

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3552232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3552232

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:38

Were any significant conditions reported?

Yes ☒

No ☐

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

Condition	URINARY RETENTION
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

Condition	WOUND RIGHT ELBOW
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

Condition	RIGHT SHOULDER DISLOCATION
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1951
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1951
Start Year (derived)	1951
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	24 JAN 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

Condition	RIGHT LOWER EXTREMITY CELLULITIS
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

Condition	DEPRESSION
Start date (dd MMM yyyy)	13 JUN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

Condition	SENSORY DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	21 JUL 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

Condition	DIVERTICULOSIS OF COLON
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	30 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

Condition	GASTRITIS
Start date (dd MMM yyyy)	10 OCT 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2011
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2011
Start Year (derived)	2011
Stop Month and Year (derived)	OCT 2011
Stop Year (derived)	2011

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

Condition	H. PYLORI INFECTION
Start date (dd MMM yyyy)	12 OCT 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2011
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2011
Start Year (derived)	2011
Stop Month and Year (derived)	OCT 2011
Stop Year (derived)	2011

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	13 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	28 APR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	01 NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	01 NOV 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2019
Stop Year (derived)	2019

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

Condition	ADENOMATOUS COLON POLYP
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	17 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

Condition	COLONSCOPY
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	17 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

Condition	PYURIA
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	18 JAN 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	08 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	18 JAN 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

Condition	CORONARY ARTERY STENT
Start date (dd MMM yyyy)	20 APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	20 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 08:10
Height (xxx.x)	68.5 in
Weight (xxx.x)	181 lb
BMI (xxx.x)	27.17736 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552232

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 AUG 2020

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

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

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

SHIPPING AT
GROCERY/HARDWARE, DINING
AT RESTAURANTS 2-3/MO.
TRAVELS BY AIRPLANE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

v6.020 DTW (1102)

40 of 3042

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 188834

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 ☒

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

Height	ND - Not Done
Weight	ND - Not Done

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 08:10
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 11:10
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3552232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 10:40

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

What was the frequency of the study treatment dosing? ONCE

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

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

29 AUG 2020

Collection time (*00:00-23:59*)

10:00 (24 HR)

Collection date and time (derived)

29 AUG 2020 10:00

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:38

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	29 AUG 2020 10:05
Nasopharyngeal Swab 2	No		

US3552232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 11:04

PC Open Date & Time

29 AUG 2020 11:00

PC Close Date & Time

29 AUG 2020 13:30

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	29 AUG 2020 15:53
PC Open Date & Time	29 AUG 2020 14:25
PC Close Date & Time	30 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

98.0 °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

30 AUG 2020 12:45

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

31 AUG 2020 12:15

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:10

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

98.0 °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

02 SEP 2020 12:19

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

03 SEP 2020 12:08

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 11:04

PC Open Date & Time

29 AUG 2020 11:00

PC Close Date & Time

29 AUG 2020 13:30

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

29 AUG 2020 15:54

PC Open Date & Time

29 AUG 2020 14:25

PC Close Date & Time

30 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

30 AUG 2020 12:45

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

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

31 AUG 2020 12:15

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

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

01 SEP 2020 12:10

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

02 SEP 2020 12:19

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

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

03 SEP 2020 12:08

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 11:08
PC Open Date & Time	29 AUG 2020 11:00
PC Close Date & Time	29 AUG 2020 13:30

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 15:55
PC Open Date & Time	29 AUG 2020 14:25
PC Close Date & Time	30 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	30 AUG 2020 12:46
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	31 AUG 2020 12:16
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	01 SEP 2020 12:11
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	02 SEP 2020 12:20
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	03 SEP 2020 12:09
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

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 ☒

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

Yes ☐	
PC Time stamp	04 SEP 2020 12:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

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

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

Was this visit performed?	Yes ☐
	No ☒

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

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

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

US3552232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3552232

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3552232

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3552232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3552232

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3552232

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:38

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3552232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:31 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 10:31
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	177 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:36 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:36

US3552232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 21:50:30
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	05 NOV 2020 16:35:20
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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	12 NOV 2020 11:13:38
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 12:17:38
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:01:53
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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°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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552232

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552232

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:37:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552232

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	CRYPTOGENIC ORGANIZING PNEUMONIA
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)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	08 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

327 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2. SUBJECT
READMITTED FOR ATRIAL
FIBRILLATION ON 10/15-10/17; X
RAY ON 10/15 SHOWED
PNEUMONIA ONGOING.UPDATE
10/30/20: SUBJECT REPORTED
TO CLINIC FOR DAY 57 VISIT;
O2 IS DOWN TO 1L/MIN WHILE
UP AND ABOUT; PNEUMONIA
AND COUGH IMPROVE.
REPORTS PER PULMONOLOGY

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

11/19 HE IS RECOVERING, 3 MON FOLLOW UP.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	RESPIRATORY FAILURE
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)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	332 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2. SUBJECT
READMITTED FOR ATRIAL
FIBRILLATION ON 10/15-10/17; X
RAY ON 10/15 SHOWED
PNEUMONIA ONGOING. PER
PULM APPT 11/19, SUBJECT IS
RECOVERING, 3 MON FOLLOW
UP GOING FORWARD.

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

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	PAROXYSMAL ATRIAL FIBRILLATION
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)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

336 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☒ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SUBJECT IS CURRENTLY IN SINUS RHYTHM, BUT COULD INTERMITTENTLY GO IN AND OUT OF ATRIAL FIBRILLATION. ON MEDICATION AND FOLLOWING UP WITH PCP TO CONTROL AND MONITOR.

Narrative

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2. SUBJECT
READMITTED FOR ATRIAL
FIBRILLATION ON 10/15-10/17; X
RAY ON 10/15 SHOWED
PNEUMONIA ONGOING.

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

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	NON-ST ELEVATED MYOCARDIAL INFARCTION
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)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	26 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

340 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2.

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

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	HYPOMAGNESIA
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)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	344 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2.

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

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

AEID	USA-US089-2020-MRNA-1273-P30 1000006
Adverse event	ACUTE KIDNEY INJURY
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)	26 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	348 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

SUBJECT CONTACTED SITE ON
9/25 WITH ALLERGY
SYMPTOMS (SNIFFLES, POST
NASAL DRAINAGE COUGH)
TYPICAL TO SUBJECT PER
SUBJECT; INSTRUCTED TO
CALL BACK IF ANYTHING
WORSENS OR CHANGES. PER
SUBJECT 9/26 WORSENING
COUGH AND FEVER OF 101.
ILLNESS VISIT SCHEDULED
9/28, SUBJECT URGED TO
CONTACT PCP OR URGENT
CARE. PER SUBJECT 9/28,
ADMITTED TO THE HOSPITAL
ON 9/26, HAD A NEGATIVE
COVID-19 SWAB AND ONGOING
COUGH AND FEVER WITH
CARDIOLOGY WORKUP. PER
INPATIENT ID PHYSICIAN
STATED SUBJECT HAS
PNEUMONIA AND
RESPIRATORY FAILURE WITH
CHEST X-RAY SUGGESTIVE OF
COVID-19 AND IS ON 6L OF O2.
9/29 UPDATE: CONDITION
WORSENING; SUBJECT ON
8L/MIN O2; DIFFUSE BILAT
INFILTRATES, POSSIBLY
ORGANIZING PNEUMONIA;
BRONCHOSCOPY PLANNED,
HAS HAD 2 NEG COVID TESTS.
SUBJECT'S BRONCHOSCOPY
ALSO NEGATIVE FOR COVID,
WEANED TO 3L, REMAINS
INPATIENT, CULTURES ARE
STILL PENDING FROM BRONCH.

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

BEING FOLLOWED BY CARDS,
PULM, AND ID, ON STEROIDS.

UPDATE 10/12: SUBJECT
DISCHARGED 10/8 ON 2L O2.
DIAGNOSED WITH NSTEMI ON
ADMISSION IN NEW ONSET
AFIB; HOLTER MONITOR ON
DISCHARGE FOR 30 DAYS.
ECHO SHOWS EF OF 35-45% AT
DISCHARGE. TROPONINS
ELEVATED ON ADMISSION,
SECONDARY TO ISCHEMIA
RELATED TO AFIB PER
RECORDS. CHEST X RAYS (9/26
& 10/6) SHOW BILAT
INFILTRATES/MULTIFOCAL
PNEUMONIA; CHEST CT WITH
SAME FINDINGS - FINAL
DIAGNOSIS OF CRYPTOGENIC
ORGANIZING PNEUMONIA,
REMAINS ON PREDNISONE.
NEGATIVE RESPIRATORY
PANEL. BRONCHOSCOPY 9/30,
CULTURES OBTAINED BUT
RESULTS NOT IN RECORDS.
PER SUBJECT REPORT AS OF
10/12, NOW ON 4L O2.

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

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

AEID	
Adverse event	NAUSEA
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)	27 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	352 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:38

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

Yes ☒

No ☐

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LANTUS
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	25
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	U
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	VICTOZA
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	1.8
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	PLAVIX
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	0.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	HYDRALAZINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	TAMULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	URINARY RETENTION
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 ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	FINASTERIDE
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTENSION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	8 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	80
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	TRAZADONE
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
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 ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

Name of Medication CORICIDIN
[DEXTROMETHORPHAN/CHLOR
OPHENIRAMINE MALEATE]

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES/NASAL
CONGESTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

v6.020 DTW (1102)

377 of 3042

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	APIXABAN
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	02 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	METOPROLOL XL
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	EFFEXOR XR
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	NON-ST ELEVATED MYOCARDIAL INFARCTION
Dose per administration	324
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 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ROCEPHIN
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	2000
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	26 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	28 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	250
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	MAGNESIUM
Prophylaxis	Yes ☐ No ☒
Indication	HYPOMAGNESIA
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	26 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived) _____	
Interval Dosage Unit Number (derived) _____	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	NORCO [HYDROCODONE/ACETAMINOPHEN]
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ONDANSETRON
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		27 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LOVENOX
Prophylaxis	Yes ☒ No ☐
Indication	COAGULATION PROPHYLAXIS
Dose per administration	80
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	TESSALON
Prophylaxis	Yes ☐ No ☒
Indication	COUGH
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	NOVOLOG
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	0-5
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	EVERY 4 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	ACUTE CORONARY SYNDROME
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	DECADRON
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	6
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	26 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒

If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ☒

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LEVAQUIN
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	750
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

Name of Medication MUCINEX DM
[DEXTROMETHORPHAN/GUAIF
ENESIN]

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 30/600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	08 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	ALBUTEROL 0.5%
Prophylaxis	Yes ☐ No ☒
Indication	BRONCHOSCOPY
Dose per administration	2.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LIDOCAINE 4%
Prophylaxis	Yes ☐ No ☒
Indication	BRONCHOSCOPY
Dose per administration	1.5
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LOVENOX
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LEVALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	.63
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	EVERY 6 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

v6.020 DTW (1102)

421 of 3042

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	DILTIAZEM
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	DIGOXIN
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	450
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	CONTINUOUS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		06 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LASIX
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	TESSALON
Prophylaxis	Yes ☐ No ☒
Indication	COUGH
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	EVERY 8 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	30
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	24 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	DILTIAZEM
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	19
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 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	DILTIAZEM
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	125
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	CONTINUOUS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ☒
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	450
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	CONTINUOUS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

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

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	LOVENOX
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	80
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	NOVOLOG
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 2
Dose per administration	2-12
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	EVERY 4 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
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 ☐ Intramuscular ☐

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:37:38

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:37:38

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
30 SEP 2020	BRONCHOSCOPY	Diagnostic	

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:38

Date of dosing discontinuation (dd MMM yyyy)

3 OCT 2020

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

SAE #3

US3552232

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:37:38

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 ☐

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	29/SEP/2020 09:22
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	30/SEP/2020 13:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	07/OCT/2020 08:13
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	09/OCT/2020 13:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	13/OCT/2020 14:57
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	16/OCT/2020 07:41
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	20/OCT/2020 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	21/OCT/2020 14:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/OCT/2020 15:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	29/OCT/2020 11:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	02/NOV/2020 13:15
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	04/NOV/2020 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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	10/NOV/2020 20:25
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	20/NOV/2020 18:03
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

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Generated On: 26 Nov 2020 09:37:38

SAEID	USA-US089-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	23/NOV/2020 14:17
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

Audit

US3552232 (Prod: Saint Louis University)

US3552232

Form: Participant Creation

Generated On: 26 Nov 2020 09:37:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552232'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 13:35:44

US3552232

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 13:35:45

US3552232

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Aug 2020 18:50:30

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 13:35:46

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Age](#)

Audit	User	Time (GMT)
User entered '70'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '70'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[White](#)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:38

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:44

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 15:14:27

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Aug 2020 13:35:45

US3552232

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:37:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:37:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:50:53

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:55:40
Data point term sent to Coder	System	12 Oct 2020 20:54:20
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:54:19
User entered 'TYPE 2 DIABETES' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:54:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:52:39
Data point term sent to Coder	System	29 Aug 2020 18:51:41
User entered 'type 1 diabetes'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 1992'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '1992'	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:51:35

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:53:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:53:40
Data point term sent to Coder	System	29 Aug 2020 18:52:42
User entered 'coronary artery disease'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2013'	System	29 Aug 2020 18:51:58

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
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) (b) (4)	29 Aug 2020 18:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:53:39
Data point term sent to Coder	System	29 Aug 2020 18:52:44
User entered 'hypertension'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 1992'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '1992'	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:52:10

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:53:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:53:40
Data point term sent to Coder	System	29 Aug 2020 18:52:44
User entered 'urinary retention'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un Nov 2019'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:52:27

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Bacteria identification and serology (excl mycobacteria), PT: Staphylococcus test positive, LLT: Methicillin-resistant Staphylococcus aureus test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:16:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:16:52
Data point term sent to Coder	System	29 Aug 2020 20:46:32
Coding entries removed.	Heather Douds (b) (4) (b) (4)	29 Aug 2020 20:45:36
User entered 'MRSA POSITIVE' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Aug 2020 20:45:36
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal infection, LLT: Infection MRSA - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
Data point term sent to Coder	System	29 Aug 2020 18:53:45
User entered 'MRSA'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2017'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2017'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 18:53:11

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
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 hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
Data point term sent to Coder	System	29 Aug 2020 18:53:45
User entered 'benign prostatic hypertrophy'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un Nov 2019'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:27

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Aug 2020 18:54:40
Data point term sent to Coder	System	29 Aug 2020 18:53:45
User entered 'insomnia'	Mikayla Frye (b) (4)	29 Aug 2020 18:53:40
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2010'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2010'	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:40

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:46
User entered 'hyperlipidemia'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2015'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2015'	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:53:59

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Diabetic retinopathy, LLT: Diabetic retinopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:45:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:45:43
Data point term sent to Coder	System	29 Aug 2020 20:46:30
Coding entries removed.	Heather Douds (b) (4) (b) (4)	29 Aug 2020 20:46:08
User entered 'DIABETIC RETINOPATHY LEFT EYE' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	29 Aug 2020 20:46:08
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Diabetic retinopathy, LLT: Diabetic retinopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:46
User entered 'diabetic retinopathy'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2019'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:14

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Ocular disorders NEC, PT: Lens disorder, LLT: Lens disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:46:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:46:36
Data point term sent to Coder	System	29 Aug 2020 18:54:48
User entered 'left lens erosion'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2019'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:26

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:48
User entered 'low back pain'	Mikayla Frye (b) (4)	29 Aug 2020 18:54:36
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2015'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2015'	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:36

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Wound, LLT: Wound - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:45:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:45:42
Data point term sent to Coder	System	29 Aug 2020 18:55:49
User entered 'wound right elbow'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:57:55
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration.' answered with 'data correct as entered' (Site from DM).	Heather Douds (b) (4) (b) (4)	08 Oct 2020 13:09:42
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:39:47
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:54:57

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Joint dislocation, LLT: Shoulder dislocation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 18:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Aug 2020 18:56:41
Data point term sent to Coder	System	29 Aug 2020 18:55:49
User entered 'right shoulder dislocation'	Mikayla Frye (b) (4)	29 Aug 2020 18:55:13
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 1975'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'un UNK 1975'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '1975'	System	29 Aug 2020 18:55:13

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:56:41
Data point term sent to Coder	System	29 Aug 2020 18:55:49
User entered 'seasonal allergies'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		29 Aug 2020 18:56:22
User entered 'UN UNK 1951' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 18:56:22
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	29 Aug 2020 18:55:26
User entered 'un UNK 1950'	System	29 Aug 2020 18:55:26
	Mikayla Frye (b) (4)	29 Aug 2020 18:55:26
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 1951'	System	29 Aug 2020 18:56:22
User entered 'Jan 1950'	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '1951'	System	29 Aug 2020 18:56:22
User entered '1950'	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:55:26

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:56:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:56:26
Data point term sent to Coder	System	12 Oct 2020 20:55:23
User entered 'Chronic Kidney Disease'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '24 Jan 2012'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2012'	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:55:10

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:46:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:46:29
Data point term sent to Coder	System	12 Oct 2020 20:56:25
User entered 'Right lower extremity cellulitis'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '08 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:38
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:38
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:55:38

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:57:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:57:30
Data point term sent to Coder	System	12 Oct 2020 20:56:25
User entered 'Depression'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '13 Jun 2008'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:03
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2008'	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2008'	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:56:03

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:55:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:55
Data point term sent to Coder	System	28 Oct 2020 19:06:53
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:06:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Oct 2020 19:06:12
Coding entries removed.	Cassandra Zehenny (b) (4)	28 Oct 2020 19:06:12
User entered 'sensory DIABETIC NEUROPATHY' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	28 Oct 2020 19:06:12
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:27:37
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	12 Oct 2020 20:57:26
User entered 'diabetic neuropathy'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '21 Jul 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jul 2014'	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:56:34

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Colonic diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20
Data point term sent to Coder	System	12 Oct 2020 20:57:26
User entered 'diverticulosis of colon'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '30 Jun 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 20:56:57

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 20:58:20
Data point term sent to Coder	System	12 Oct 2020 20:57:27
User entered 'GASTRITIS'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '10 Oct 2011'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:21
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '31 Oct 2011'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Oct 2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Oct 2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2011'	System	12 Oct 2020 20:57:21

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Helicobacter infections, PT: Helicobacter infection, LLT: Helicobacter pylori infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:59:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:59:21
Data point term sent to Coder	System	12 Oct 2020 20:58:28
User entered 'h. pYLORI INFECTION'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '12 Oct 2011'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:46
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '31 Oct 2011'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Oct 2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Oct 2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2011'	System	12 Oct 2020 20:57:46

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 21:00:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 21:00:24
Data point term sent to Coder	System	12 Oct 2020 20:59:30
User entered 'iron deficiency anemia'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '13 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:27
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:59:27

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:01:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:01:31
Data point term sent to Coder	System	12 Oct 2020 21:00:31
User entered 'mitral valve regurgitation'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '28 Apr 2016'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Apr 2016'	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2016'	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:59:54

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:01:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:01:31
Data point term sent to Coder	System	12 Oct 2020 21:00:32
User entered 'myocardial infarction'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '01 Nov 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '01 Nov 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:14
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:00:14

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms benign, HLT: Lower gastrointestinal neoplasms benign, PT: Colon adenoma, LLT: Colon adenomatous polyp - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:02:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:02:18
Data point term sent to Coder	System	12 Oct 2020 21:01:32
User entered 'Adenomatous colon polyp'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 21:33:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 21:33:07
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	12 Oct 2020 21:33:07
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 21:00:58
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:00:58

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Investigations, HLG: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:14:17
Data point term sent to Coder	System	12 Oct 2020 21:13:50
User entered 'colonoscopy'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '17 Jun 2019'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:04
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Oct 2020 21:13:04

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Exposures, chemical injuries and poisoning, HLT: Exposures to agents or circumstances NEC, PT: Exposure to communicable disease, LLT: Tuberculosis exposure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:14:17
Data point term sent to Coder	System	12 Oct 2020 21:13:51
User entered 'Tuberculosis exposure'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	12 Oct 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 21:13:41
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:13:41

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Pyuria, LLT: Pyuria - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 21:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Oct 2020 21:15:19
Data point term sent to Coder	System	12 Oct 2020 21:14:52
User entered 'Pyuria'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:04
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '08 Jan 2014'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '18 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 21:14:04

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 21:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 21:15:19
Data point term sent to Coder	System	12 Oct 2020 21:14:56
User entered 'pulmonary embolism'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '08 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:11:26
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' answered with 'embolism turned septic, had to be hospitalized in 2014. Took 10 days to dissolve clot ' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:08:02
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:28:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '18 Jan 2014'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2014'	System	12 Oct 2020 21:14:48

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary arterial stent insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:17:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:17:22
Data point term sent to Coder	System	12 Oct 2020 21:15:56
User entered 'coronary artery stent'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '20 Apr 2018'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:13
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '20 Apr 2018'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:13
	(b) (4)	

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Oct 2020 21:15:13

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:05
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'subject did not have UTI needing treatment within 30 days of screening visit' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:08:38
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:29:25
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Recurrent urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 21:17:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Oct 2020 21:17:22
Data point term sent to Coder	System	12 Oct 2020 21:15:58
User entered 'recurrent urinary tract infections'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Medical History (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 21:15:40

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '08:10'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 08:10'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '68.5' in	Mikayla Frye (b) (4)	29 Aug 2020 18:56:55
DataPoint set to visible.	(b) (4) System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '181' lb	Mikayla Frye (b) (4)	29 Aug 2020 18:56:55
DataPoint set to visible.	(b) (4) System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '27.17736'	System	29 Aug 2020 18:56:55
DataPoint set to visible.	System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Aug 2020 18:56:55
DataPoint set to visible.	System	29 Aug 2020 15:14:32

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:56:55

US3552232

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:01

US3552232

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:01

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

[Specify](#)

Audit	User	Time (GMT)
User entered 'shipping at grocery/hardware, dining at restaurants 2-3/mo. travels by airplane'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

Other

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:57:57

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Aug 2020 18:58:06

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 15:15:41

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '188834'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 15:15:41

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Aug 2020 15:15:41

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	14 Sep 2020 19:19:52
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:58:15

US3552232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4)	21 Sep 2020 17:38:52
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:35:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:35:51

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:10'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 08:10'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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)	02 Sep 2020 18:50:55
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 'NCS' (Site from System).	Heather Douds (b) (4)	31 Aug 2020 18:32:21
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	29 Aug 2020 18:59:23
User entered '156'	Mikayla Frye (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:38

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:10'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:10'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '146'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:59:23

US3552232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:13

US3552232

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:13

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:40'	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:40'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 15:45:14

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:00'	System	29 Aug 2020 19:01:24

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '10:05'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 10:05'	System	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 19:01:33

US3552232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 16:48:12

US3552232

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:48:12

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:03:49', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f54b7d82-8970-4dc9-90f7-65a4d1ed2fd2'	System	29 Aug 2020 16:04:22
User entered 'Yes (Y)'	System	29 Aug 2020 16:04:22

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f54b7d82-8970-4dc9-90f7-65a4d1ed2fd2'	System	29 Aug 2020 16:04:22
User entered '97.9'	System	29 Aug 2020 16:04:22

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:08', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f54b7d82-8970-4dc9-90f7-65a4d1ed2fd2'	System	29 Aug 2020 16:04:22
User entered 'No (N)'	System	29 Aug 2020 16:04:22

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:17', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f54b7d82-8970-4dc9-90f7-65a4d1ed2fd2'	System	29 Aug 2020 16:04:22
User entered '29 Aug 2020 11:04'	System	29 Aug 2020 16:04:22

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:30'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:53:22', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '9d53771f-fe64-4777-93d9-69d072ae824c'	System	29 Aug 2020 20:53:49
User entered 'Yes (Y)'	System	29 Aug 2020 20:53:49

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:53:34', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '9d53771f-fe64-4777-93d9-69d072ae824c'	System	29 Aug 2020 20:53:49
User entered '97.6'	System	29 Aug 2020 20:53:49

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:53:40', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '9d53771f-fe64-4777-93d9-69d072ae824c'	System	29 Aug 2020 20:53:49
User entered 'No (N)'	System	29 Aug 2020 20:53:49

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:53:47', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '9d53771f-fe64-4777-93d9-69d072ae824c'	System	29 Aug 2020 20:53:49
User entered '29 Aug 2020 15:53'	System	29 Aug 2020 20:53:49

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:25'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 2'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5cac25dd-6924-453b-b40e-c7586e664eae'	System	30 Aug 2020 17:45:30
User entered 'Yes (Y)'	System	30 Aug 2020 17:45:30

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:12', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5cac25dd-6924-453b-b40e-c7586e664eae'	System	30 Aug 2020 17:45:30
User entered '98.0'	System	30 Aug 2020 17:45:30

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:16', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5cac25dd-6924-453b-b40e-c7586e664eae'	System	30 Aug 2020 17:45:30
User entered 'No (N)'	System	30 Aug 2020 17:45:30

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:26', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5cac25dd-6924-453b-b40e-c7586e664eae'	System	30 Aug 2020 17:45:30
User entered '30 Aug 2020 12:45'	System	30 Aug 2020 17:45:30

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 3'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:01', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70a6956e-5301-4db6-8fa7-a0b741715421'	System	31 Aug 2020 17:24:38
User entered 'Yes (Y)'	System	31 Aug 2020 17:24:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:18', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70a6956e-5301-4db6-8fa7-a0b741715421'	System	31 Aug 2020 17:24:38
User entered '97.8'	System	31 Aug 2020 17:24:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:22', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70a6956e-5301-4db6-8fa7-a0b741715421'	System	31 Aug 2020 17:24:38
User entered 'No (N)'	System	31 Aug 2020 17:24:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:29', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '70a6956e-5301-4db6-8fa7-a0b741715421'	System	31 Aug 2020 17:24:38
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 17:24:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 4'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:09:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '02a67e03-9eb2-4765-bb1f-c3f6923379e6'	System	01 Sep 2020 17:10:09
User entered 'Yes (Y)'	System	01 Sep 2020 17:10:09

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:09:50', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '02a67e03-9eb2-4765-bb1f-c3f6923379e6'	System	01 Sep 2020 17:10:09
User entered '98.4'	System	01 Sep 2020 17:10:09

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:09:55', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '02a67e03-9eb2-4765-bb1f-c3f6923379e6'	System	01 Sep 2020 17:10:09
User entered 'No (N)'	System	01 Sep 2020 17:10:09

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '02a67e03-9eb2-4765-bb1f-c3f6923379e6'	System	01 Sep 2020 17:10:09
User entered '01 Sep 2020 12:10'	System	01 Sep 2020 17:10:09

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 5'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:11', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '862e45f9-1fe1-4284-8b55-be2ef13d6f22'	System	02 Sep 2020 17:19:33
User entered 'Yes (Y)'	System	02 Sep 2020 17:19:33

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:22', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '862e45f9-1fe1-4284-8b55-be2ef13d6f22'	System	02 Sep 2020 17:19:33
User entered '98.0'	System	02 Sep 2020 17:19:33

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:26', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '862e45f9-1fe1-4284-8b55-be2ef13d6f22'	System	02 Sep 2020 17:19:33
User entered 'No (N)'	System	02 Sep 2020 17:19:33

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:30', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '862e45f9-1fe1-4284-8b55-be2ef13d6f22'	System	02 Sep 2020 17:19:33
User entered '02 Sep 2020 12:19'	System	02 Sep 2020 17:19:33

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 6'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:11', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5d1e967b-448c-4658-a127-39cf5bf39552'	System	03 Sep 2020 17:08:38
User entered 'Yes (Y)'	System	03 Sep 2020 17:08:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:25', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5d1e967b-448c-4658-a127-39cf5bf39552'	System	03 Sep 2020 17:08:38
User entered '97.6'	System	03 Sep 2020 17:08:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:28', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5d1e967b-448c-4658-a127-39cf5bf39552'	System	03 Sep 2020 17:08:38
User entered 'No (N)'	System	03 Sep 2020 17:08:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:32', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '5d1e967b-448c-4658-a127-39cf5bf39552'	System	03 Sep 2020 17:08:38
User entered '03 Sep 2020 12:08'	System	03 Sep 2020 17:08:38

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 7'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:19:25', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b70b751d-47b9-4a43-9d3a-7e6c7e137a65'	System	04 Sep 2020 17:20:07
User entered 'Yes (Y)'	System	04 Sep 2020 17:20:07

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:19:49', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b70b751d-47b9-4a43-9d3a-7e6c7e137a65'	System	04 Sep 2020 17:20:07
User entered '97.8'	System	04 Sep 2020 17:20:07

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:19:55', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b70b751d-47b9-4a43-9d3a-7e6c7e137a65'	System	04 Sep 2020 17:20:07
User entered 'No (N)'	System	04 Sep 2020 17:20:07

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:03', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b70b751d-47b9-4a43-9d3a-7e6c7e137a65'	System	04 Sep 2020 17:20:07
User entered '04 Sep 2020 12:20'	System	04 Sep 2020 17:20:07

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:27', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fb55ffc3-739b-463a-85f4-b68d3602e222'	System	29 Aug 2020 16:04:49
User entered 'None (1)'	System	29 Aug 2020 16:04:49

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:31', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fb55ffc3-739b-463a-85f4-b68d3602e222'	System	29 Aug 2020 16:04:49
User entered 'No (N)'	System	29 Aug 2020 16:04:49

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:35', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fb55ffc3-739b-463a-85f4-b68d3602e222'	System	29 Aug 2020 16:04:49
User entered 'No (N)'	System	29 Aug 2020 16:04:49

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:40', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fb55ffc3-739b-463a-85f4-b68d3602e222'	System	29 Aug 2020 16:04:49
User entered 'None (1)'	System	29 Aug 2020 16:04:49

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:04:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'fb55ffc3-739b-463a-85f4-b68d3602e222'	System	29 Aug 2020 16:04:49
User entered '29 Aug 2020 11:04'	System	29 Aug 2020 16:04:49

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:30'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:06', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '890b7d60-3d24-4b5f-b85d-1f2606e9675c'	System	29 Aug 2020 20:54:29
User entered 'None (1)'	System	29 Aug 2020 20:54:29

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:11', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '890b7d60-3d24-4b5f-b85d-1f2606e9675c'	System	29 Aug 2020 20:54:29
User entered 'No (N)'	System	29 Aug 2020 20:54:29

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:15', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '890b7d60-3d24-4b5f-b85d-1f2606e9675c'	System	29 Aug 2020 20:54:29
User entered 'No (N)'	System	29 Aug 2020 20:54:29

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '890b7d60-3d24-4b5f-b85d-1f2606e9675c'	System	29 Aug 2020 20:54:29
User entered 'None (1)'	System	29 Aug 2020 20:54:29

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:27', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '890b7d60-3d24-4b5f-b85d-1f2606e9675c'	System	29 Aug 2020 20:54:29
User entered '29 Aug 2020 15:54'	System	29 Aug 2020 20:54:29

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:25'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 2'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:35', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1e8b4109-4928-4bc2-8864-01406c64f4c4'	System	30 Aug 2020 17:45:58
User entered 'None (1)'	System	30 Aug 2020 17:45:58

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:39', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1e8b4109-4928-4bc2-8864-01406c64f4c4'	System	30 Aug 2020 17:45:58
User entered 'No (N)'	System	30 Aug 2020 17:45:58

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:43', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1e8b4109-4928-4bc2-8864-01406c64f4c4'	System	30 Aug 2020 17:45:58
User entered 'No (N)'	System	30 Aug 2020 17:45:58

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:47', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1e8b4109-4928-4bc2-8864-01406c64f4c4'	System	30 Aug 2020 17:45:58
User entered 'None (1)'	System	30 Aug 2020 17:45:58

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:45:53', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '1e8b4109-4928-4bc2-8864-01406c64f4c4'	System	30 Aug 2020 17:45:58
User entered '30 Aug 2020 12:45'	System	30 Aug 2020 17:45:58

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 3'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:37', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8546906-3237-49e4-baaf-0a3f47b03abd'	System	31 Aug 2020 17:24:42
User entered 'None (1)'	System	31 Aug 2020 17:24:42

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:41', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8546906-3237-49e4-baaf-0a3f47b03abd'	System	31 Aug 2020 17:24:42
User entered 'No (N)'	System	31 Aug 2020 17:24:42

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:44', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8546906-3237-49e4-baaf-0a3f47b03abd'	System	31 Aug 2020 17:24:42
User entered 'No (N)'	System	31 Aug 2020 17:24:42

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8546906-3237-49e4-baaf-0a3f47b03abd'	System	31 Aug 2020 17:24:42
User entered 'None (1)'	System	31 Aug 2020 17:24:42

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:52', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8546906-3237-49e4-baaf-0a3f47b03abd'	System	31 Aug 2020 17:24:42
User entered '31 Aug 2020 12:15'	System	31 Aug 2020 17:24:42

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 4'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:10', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4b35337b-d227-44f1-8ad7-c62410001900'	System	01 Sep 2020 17:10:31
User entered 'None (1)'	System	01 Sep 2020 17:10:31

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:14', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4b35337b-d227-44f1-8ad7-c62410001900'	System	01 Sep 2020 17:10:31
User entered 'No (N)'	System	01 Sep 2020 17:10:31

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:17', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4b35337b-d227-44f1-8ad7-c62410001900'	System	01 Sep 2020 17:10:31
User entered 'No (N)'	System	01 Sep 2020 17:10:31

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4b35337b-d227-44f1-8ad7-c62410001900'	System	01 Sep 2020 17:10:31
User entered 'None (1)'	System	01 Sep 2020 17:10:31

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:26', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4b35337b-d227-44f1-8ad7-c62410001900'	System	01 Sep 2020 17:10:31
User entered '01 Sep 2020 12:10'	System	01 Sep 2020 17:10:31

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 5'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:36', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '47dab7e9-1ae1-4a0e-a4d5-3389b6f3f2e8'	System	02 Sep 2020 17:19:56
User entered 'None (1)'	System	02 Sep 2020 17:19:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:40', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '47dab7e9-1ae1-4a0e-a4d5-3389b6f3f2e8'	System	02 Sep 2020 17:19:56
User entered 'No (N)'	System	02 Sep 2020 17:19:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:43', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '47dab7e9-1ae1-4a0e-a4d5-3389b6f3f2e8'	System	02 Sep 2020 17:19:56
User entered 'No (N)'	System	02 Sep 2020 17:19:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:47', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '47dab7e9-1ae1-4a0e-a4d5-3389b6f3f2e8'	System	02 Sep 2020 17:19:56
User entered 'None (1)'	System	02 Sep 2020 17:19:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:19:54', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '47dab7e9-1ae1-4a0e-a4d5-3389b6f3f2e8'	System	02 Sep 2020 17:19:56
User entered '02 Sep 2020 12:19'	System	02 Sep 2020 17:19:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 6'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:37', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7fd01f82-2911-4a86-b521-794df0f88670'	System	03 Sep 2020 17:08:56
User entered 'None (1)'	System	03 Sep 2020 17:08:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:41', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7fd01f82-2911-4a86-b521-794df0f88670'	System	03 Sep 2020 17:08:56
User entered 'No (N)'	System	03 Sep 2020 17:08:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:44', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7fd01f82-2911-4a86-b521-794df0f88670'	System	03 Sep 2020 17:08:56
User entered 'No (N)'	System	03 Sep 2020 17:08:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7fd01f82-2911-4a86-b521-794df0f88670'	System	03 Sep 2020 17:08:56
User entered 'None (1)'	System	03 Sep 2020 17:08:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:52', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '7fd01f82-2911-4a86-b521-794df0f88670'	System	03 Sep 2020 17:08:56
User entered '03 Sep 2020 12:08'	System	03 Sep 2020 17:08:56

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 7'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:12', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '722c03e7-e66c-4587-8a6e-bce1d617b5d8'	System	04 Sep 2020 17:20:34
User entered 'None (1)'	System	04 Sep 2020 17:20:34

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:16', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '722c03e7-e66c-4587-8a6e-bce1d617b5d8'	System	04 Sep 2020 17:20:34
User entered 'No (N)'	System	04 Sep 2020 17:20:34

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '722c03e7-e66c-4587-8a6e-bce1d617b5d8'	System	04 Sep 2020 17:20:34
User entered 'No (N)'	System	04 Sep 2020 17:20:34

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:24', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '722c03e7-e66c-4587-8a6e-bce1d617b5d8'	System	04 Sep 2020 17:20:34
User entered 'None (1)'	System	04 Sep 2020 17:20:34

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:31', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '722c03e7-e66c-4587-8a6e-bce1d617b5d8'	System	04 Sep 2020 17:20:34
User entered '04 Sep 2020 12:20'	System	04 Sep 2020 17:20:34

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:07:46', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:07:51', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:07:55', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:07:59', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:08:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:08:05', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'None (0)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:08:12', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered 'No (N)'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T11:08:19', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e2ef2fbb-f293-4ee3-a343-393e2aec6f0f'	System	29 Aug 2020 16:08:23
User entered '29 Aug 2020 11:08'	System	29 Aug 2020 16:08:23

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 13:30'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:34', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:38', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:41', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:44', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:52', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'None (0)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:54:56', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered 'No (N)'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-29T15:55:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'f2302562-34aa-4423-b34b-f115c817d85e'	System	29 Aug 2020 20:55:05
User entered '29 Aug 2020 15:55'	System	29 Aug 2020 20:55:05

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 14:25'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 2'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:01', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:04', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:07', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:10', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:13', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:16', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'None (0)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered 'No (N)'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-30T12:46:24', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '854a55d4-e582-4033-9303-9c6c261074b4'	System	30 Aug 2020 17:46:27
User entered '30 Aug 2020 12:46'	System	30 Aug 2020 17:46:27

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 3'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:15:58', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:06', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:10', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:13', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:16', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'None (0)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered 'No (N)'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-08-31T12:16:25', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'b8683948-3743-410f-b1e5-d7d0b4e08615'	System	31 Aug 2020 17:24:48
User entered '31 Aug 2020 12:16'	System	31 Aug 2020 17:24:48

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 4'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:34', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:39', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:44', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:51', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:54', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'None (0)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:10:58', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered 'No (N)'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-01T12:11:01', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '3255dd24-3f5c-4ab8-92b9-95be2799a49d'	System	01 Sep 2020 17:11:03
User entered '01 Sep 2020 12:11'	System	01 Sep 2020 17:11:03

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 5'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:02', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:05', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:09', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:12', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:15', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:18', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'None (0)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered 'No (N)'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-02T12:20:26', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '60ab7651-4938-495b-9ac7-10b43a7f5308'	System	02 Sep 2020 17:20:29
User entered '02 Sep 2020 12:20'	System	02 Sep 2020 17:20:29

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 6'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:08:57', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:03', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:07', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:10', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:13', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'None (0)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:17', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered 'No (N)'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-03T12:09:21', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'd34eefe-9fe0-47c2-8bc2-d60bd12ef1f0'	System	03 Sep 2020 17:09:25
User entered '03 Sep 2020 12:09'	System	03 Sep 2020 17:09:25

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 7'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:36', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:40', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:45', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:52', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:20:55', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'None (0)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:21:04', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered 'No (N)'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-09-04T12:21:08', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '8cd26764-3c49-48ac-909e-83416045d5ed'	System	04 Sep 2020 17:21:12
User entered '04 Sep 2020 12:21'	System	04 Sep 2020 17:21:12

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:45:14

US3552232

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:35:29
User entered '5 Sep 2020'	Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 16:48:25

US3552232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:40

US3552232

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 18:55:40

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Sep 2020 18:55:49

US3552232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:30

US3552232

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Sep 2020 17:18:30

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	19 Sep 2020 17:18:37

US3552232

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:02:36

US3552232

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:02:36

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:02:51

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:02:51

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:02:51

US3552232

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 20:02:51

US3552232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:02:58

US3552232

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:02:58

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:32

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:32

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:32

US3552232

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:32

US3552232

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:39

US3552232

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:03:39

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:49

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:49

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:49

US3552232

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 20:03:49

US3552232

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:26

US3552232

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:35:26

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:35:38

US3552232

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:20:18

US3552232

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 18:20:18

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	30 Oct 2020 18:21:01

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17
	(b) (4)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Doublin (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:31' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 10:31'	System	30 Oct 2020 18:48:48
User entered empty.	System	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '98.0' F reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Doublin (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17
	(b) (4)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 18:48:48
User entered empty.	System	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '17' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17
	(b) (4)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 18:48:48
User entered empty.	System	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '177' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 18:48:48
User entered empty.	System	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '93' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:48:48
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:17
	(b) (4)	

US3552232

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 18:48:48
User entered empty.	System	30 Oct 2020 18:21:17

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	30 Oct 2020 18:23:05
User entered 'No (N)'	Stanley Dublin (b) (4)	30 Oct 2020 18:21:41

US3552232

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:38

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	30 Oct 2020 18:23:05
User entered empty.	Stanley Dublin (b) (4)	30 Oct 2020 18:21:41

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:57

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 30OCT2020. However, collection date is missing in GCL. Please confirm if 30OCT2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:47:43
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 30OCT2020. However, collection date is missing in GCL. Please confirm if 30OCT2020 is correct date to update in GCL records. ' answered with 'subject has poor venous access and blood draw was short; date is correct as entered' (Site from DM).	Heather Douds (b) (4)	12 Nov 2020 14:21:30
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 30OCT2020. However, collection date is missing in GCL. Please confirm if 30OCT2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:21:50
User entered '30 Oct 2020'	Stanley Dublin (b) (4)	30 Oct 2020 18:21:57

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:36'	Stanley Dublin (b) (4) (b) (4)	30 Oct 2020 18:21:57

US3552232

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:36'	System	30 Oct 2020 18:21:57

US3552232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:50

US3552232

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 15:53:50

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 64'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 (6f5c0c85be35c806)', Time: '2020-10-29T21:49:58', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '01cc1eef-5fb3-446f-b7e4-3e4f169b31f8'	System	30 Oct 2020 02:50:40
User entered 'No (N)'	System	30 Oct 2020 02:50:40

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Have you been exposed to someone with 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 (6f5c0c85be35c806)', Time: '2020-10-29T21:50:10', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '01cc1eef-5fb3-446f-b7e4-3e4f169b31f8'	System	30 Oct 2020 02:50:40
User entered 'Yes (Y)'	System	30 Oct 2020 02:50:40

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

Please 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 (6f5c0c85be35c806)', Time: '2020-10-29T21:50:19', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '01cc1eef-5fb3-446f-b7e4-3e4f169b31f8'	System	30 Oct 2020 02:50:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Oct 2020 02:50:40

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-10-29T21:50:30', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '01cc1eef-5fb3-446f-b7e4-3e4f169b31f8'	System	30 Oct 2020 02:50:40
User entered '29 Oct 2020 21:50:30'	System	30 Oct 2020 02:50:40

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 71'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 (6f5c0c85be35c806)', Time: '2020-11-05T16:34:47', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '56f462ee-ecff-4efc-859c-65937b4390b2'	System	05 Nov 2020 22:35:22
User entered 'Yes (Y)'	System	05 Nov 2020 22:35:22

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Have you been exposed to someone with 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 (6f5c0c85be35c806)', Time: '2020-11-05T16:34:55', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '56f462ee-ecff-4efc-859c-65937b4390b2'	System	05 Nov 2020 22:35:22
User entered 'No (N)'	System	05 Nov 2020 22:35:22

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

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 (6f5c0c85be35c806)', Time: '2020-11-05T16:35:00', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '56f462ee-ecff-4efc-859c-65937b4390b2'	System	05 Nov 2020 22:35:22
User entered 'No (N)'	System	05 Nov 2020 22:35:22

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[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 (6f5c0c85be35c806)', Time: '2020-11-05T16:35:07', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '56f462ee-ecff-4efc-859c-65937b4390b2'	System	05 Nov 2020 22:35:22
User entered 'No (N)'	System	05 Nov 2020 22:35:22

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-11-05T16:35:20', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '56f462ee-ecff-4efc-859c-65937b4390b2'	System	05 Nov 2020 22:35:22
User entered '05 Nov 2020 16:35:20'	System	05 Nov 2020 22:35:22

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered 'Day 78'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[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 (6f5c0c85be35c806)', Time: '2020-11-12T11:13:17', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4f80f0e0-e475-4c75-b634-9d0710ea92b0'	System	12 Nov 2020 17:13:39
User entered 'No (N)'	System	12 Nov 2020 17:13:39

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Have you been exposed to someone with 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 (6f5c0c85be35c806)', Time: '2020-11-12T11:13:23', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4f80f0e0-e475-4c75-b634-9d0710ea92b0'	System	12 Nov 2020 17:13:39
User entered 'No (N)'	System	12 Nov 2020 17:13:39

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-11-12T11:13:38', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '4f80f0e0-e475-4c75-b634-9d0710ea92b0'	System	12 Nov 2020 17:13:39
User entered '12 Nov 2020 11:13:38'	System	12 Nov 2020 17:13:39

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 15:45:14

US3552232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 15:45:14
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 15:45:14

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[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 (6f5c0c85be35c806)', Time: '2020-11-20T12:17:15', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e4f3f211-84e9-4a71-91b2-0ef84f7e16c6'	System	20 Nov 2020 18:17:44
User entered 'No (N)'	System	20 Nov 2020 18:17:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

Have you been exposed to someone with 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 (6f5c0c85be35c806)', Time: '2020-11-20T12:17:25', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e4f3f211-84e9-4a71-91b2-0ef84f7e16c6'	System	20 Nov 2020 18:17:44
User entered 'No (N)'	System	20 Nov 2020 18:17:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-11-20T12:17:38', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: 'e4f3f211-84e9-4a71-91b2-0ef84f7e16c6'	System	20 Nov 2020 18:17:44
User entered '20 Nov 2020 12:17:38'	System	20 Nov 2020 18:17:44

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[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 (6f5c0c85be35c806)', Time: '2020-11-23T12:01:41', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '165c8e62-10f3-4c0c-bf25-aa0653f21276'	System	23 Nov 2020 18:01:59
User entered 'No (N)'	System	23 Nov 2020 18:01:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

Have you been exposed to someone with 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 (6f5c0c85be35c806)', Time: '2020-11-23T12:01:48', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '165c8e62-10f3-4c0c-bf25-aa0653f21276'	System	23 Nov 2020 18:01:59
User entered 'No (N)'	System	23 Nov 2020 18:01:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6f5c0c85be35c806)', Time: '2020-11-23T12:01:53', User OID: 'PatientReportedOutcome (US3552232)', ODM File OID: '165c8e62-10f3-4c0c-bf25-aa0653f21276'	System	23 Nov 2020 18:01:59
User entered '23 Nov 2020 12:01:53'	System	23 Nov 2020 18:01:59

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:27:20

US3552232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:27:20
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:27:20

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mikayla Frye (b) (4) (b) (4)	18 Nov 2020 15:53:59

US3552232

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:37:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:25
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:42:23

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered	(b) (4), (b) (6)	29 Sep 2020 13:21:58
'USA-US089-2020-mRNA-1273-P301000006'		

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:49
User closed query 'PV Query: The discharge summary reports "Community acquired pneumonia" as the diagnosis. Please consider updating the reported event term from "pneumonia" to "community acquired pneumonia".' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:14:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Organising pneumonia, LLT: Cryptogenic organizing pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 19:07:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	30 Oct 2020 19:07:58
Data point term sent to Coder	System	30 Oct 2020 18:51:52
Query 'PV Query: The discharge summary reports "Community acquired pneumonia" as the diagnosis. Please consider updating the reported event term from "pneumonia" to "community acquired pneumonia".' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	30 Oct 2020 18:51:03
DataPoint Un-verified.	Joan Siegner (b) (4)	30 Oct 2020 18:50:54
Coding entries removed.	Joan Siegner (b) (4)	30 Oct 2020 18:50:54
User entered 'cryptogenic organizing pneumonia' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 18:50:54
User opened query 'PV Query: The discharge summary reports "Community acquired pneumonia" as the diagnosis. Please consider updating the reported event term from "pneumonia" to "community acquired pneumonia".' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:38:39
User closed query 'Per MM: Please confirm the action taken with IP. If the event is present at the time scheduled for dosing, the participant may be injected at a later date, per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:37:06

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: Please confirm the action taken with IP. If the event is present at the time scheduled for dosing, the participant may be injected at a later date, per protocol 7.2' answered with 'Pneumonia still ongoing at this time; IP held for respiratory failure (see AE #3)' (Site from DM).	Heather Douds (b) (4)	21 Oct 2020 13:16:50
User opened query 'Per MM: Please confirm the action taken with IP. If the event is present at the time scheduled for dosing, the participant may be injected at a later date, per protocol 7.2' (Site from DM).	(b) (4)	20 Oct 2020 07:48:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 16:55:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	28 Sep 2020 16:55:37
Data point term sent to Coder	System	28 Sep 2020 16:55:04
User entered 'Pneumonia'	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:30
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:32
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:42:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:32:09
Query 'Data is required. Please complete.' answered with 'Unknown at this time, ongoing workup' (Site from System).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:39
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:54:27
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:42:52
User closed query 'Please verify start date, subject was hospitalized / worsening cough and fever reported on 26Sep. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:32:21
Query 'Please verify start date, subject was hospitalized / worsening cough and fever reported on 26Sep. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 14:21:37
User entered '26 Sep 2020' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 14:21:32
User opened query 'Please verify start date, subject was hospitalized / worsening cough and fever reported on 26Sep. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:29:39
User entered '28 Sep 2020'	Heather Douds (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:42:54
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:47
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Nov 2020 16:48:49
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:49
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Nov 2020 16:48:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:48
User entered 'Yes (Y)'	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:29
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 19:24:27
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 19:24:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:33:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:59
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
User entered '08 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
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)	30 Oct 2020 14:36:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:50
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 14:26:04
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).	Cassandra Zehenny (b) (4)	20 Oct 2020 21:13:30
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)	07 Oct 2020 12:43:11
User entered empty.	Heather Douds (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:53
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:42:58
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:01
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:03
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	28 Sep 2020 16:54:56
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	28 Sep 2020 16:54:27
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:51
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:49
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:47
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:32:16
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 'unknown at this time' (Site from System).	Heather Douds (b) (4)	28 Sep 2020 16:55:04
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)	28 Sep 2020 16:54:56
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	28 Sep 2020 16:54:56
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	28 Sep 2020 16:54:56
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 16:54:56
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)	28 Sep 2020 16:54:27
User entered '0'	System	28 Sep 2020 16:54:27
	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:53
User entered '26 Sep 2020'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:33
User entered '08 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	20 Nov 2020 19:24:46
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	20 Nov 2020 19:23:16
	(b) (4)	
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 19:23:16
	(b) (4)	
User closed query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:32:10
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:50
	(b) (4)	
Query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	12 Oct 2020 20:26:21
	(b) (4)	
User entered '8 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	12 Oct 2020 20:26:12
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge dates when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:08:58
	(b) (4)	
Query 'PV Query: Please provide the hospital discharge dates when available.' answered with 'duplicate query; subject remains inpatient at this time, medical records to be obtained upon discharge' (Site from Safety).	Heather Douds (b) (4)	08 Oct 2020 13:19:08
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge dates when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:42:50
	(b) (4)	
User opened query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:35:28
	(b) (4)	
User entered empty.	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 05:32:13
	(b) (4), (b) (6)	14 Oct 2020 15:29:57
Query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:26:25
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:26:12
User opened query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:32:31
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:32:20
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Unknown at this time' (Site from System).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:55:11
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	28 Sep 2020 16:54:27
User entered 'Unknown (UNK)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:00
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:01
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:05
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:30:03
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4)	08 Oct 2020 18:59:48
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:08
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:09
User entered 'None (NONE)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:11
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:12
User entered '1'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:14
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:48
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 19:23:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 19:23:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:38
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:33:33
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:49:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Oct 2020 20:26:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:43:24
User entered 'Unknown (UNKNOWN)'	Heather Douds (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:49
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 19:23:16
User entered empty; reason for change New Information	(b) (4)	
	Heather Douds (b) (4)	20 Nov 2020 19:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:36
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
	(b) (4)	
User entered 'Subject has completed his antibiotic trials, but remains on home oxygen that is being weaned. Currently on 1L NC.' reason for change:	Cassandra Zehenny (b) (4)	03 Nov 2020 16:48:35
	(b) (4)	
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:18
User entered empty.	Heather Douds (b) (4)	28 Sep 2020 16:54:27
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:46:51
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:23:16

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:23:16

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17; X RAY ON 10/15 SHOWED PNEUMONIA ONGOING.UPDATE 10/30/20: SUBJECT REPORTED TO CLINIC FOR DAY 57 VISIT; O2 IS DOWN TO 1L/MIN WHILE UP AND ABOUT; PNEUMONIA AND COUGH IMPROVE. Reports per pulmonology 11/19 he is recovering, 3 mon follow up.' reason for change: New Information		
User closed query 'PV Query: Per narrative, a follow-up chest CT was recommended. Please confirm if an additional chest CT, urine antigen or respiratory panel were completed after the subject was discharged from the hospital on 17 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:03:08
Query 'PV Query: Per narrative, a follow-up chest CT was recommended. Please confirm if an additional chest CT, urine antigen or respiratory panel were completed after the subject was discharged from the hospital on 17 Oct 2020.' answered with 'No updates have been reported. ' (Site from Safety).	Cassandra Zehenny (b) (4)	19 Nov 2020 19:59:20
User opened query 'PV Query: Per narrative, a follow-up chest CT was recommended. Please confirm if an additional chest CT, urine antigen or respiratory panel were completed after the subject was discharged from the hospital on 17 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:13:02
User closed query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:24:18
Query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital' answered with 'Results are in medical records' (Site from Safety).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:38:08
User opened query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:10:30
v6.020 DTW (1102)		1598 of 3042

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:34
User closed query 'PV Query: Please clarify if the reported cough and fever are symptoms of the pneumonia. If yes, these would not need to be reported as separate SAEs and can be removed.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:33:45
User closed query 'PV Query: The discharge summary reports sepsis as a diagnosis. Please assess if this should be reported as a separate SAE.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:33:42
User closed query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:33:38
Query 'PV Query: The discharge summary reports sepsis as a diagnosis. Please assess if this should be reported as a separate SAE.' answered with 'Sepsis is a result of pneumonia, already captured' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:53:26
Query 'PV Query: Please clarify if the reported cough and fever are symptoms of the pneumonia. If yes, these would not need to be reported as separate SAEs and can be removed.' answered with 'updated; queries removed as per query request' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:52:40
Query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital.' answered with 'result of CT scan is provided in discharge summary already acquired.' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:49:34
User closed query 'PV Query: Please provide follow up on the subject's condition since discharge.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:14:15
Query 'PV Query: Please provide follow up on the subject's condition since discharge.' answered with 'done' (Site from Safety).	Joan Siegner (b) (4)	30 Oct 2020 18:55:29
DataPoint Un-verified.	Joan Siegner (b) (4)	30 Oct 2020 18:55:14

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Joan Siegner (b) (4)	30 Oct 2020 18:55:14

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17; X RAY ON 10/15 SHOWED PNEUMONIA ONGOING.Update 10/30/20: Subject reported to clinic for Day 57 visit; O2 is down to 1L/min while up and about; pneumonia and cough improve.' reason for change: New Information		
User opened query 'PV Query: Please clarify if the reported cough and fever are symptoms of the pneumonia. If yes, these would not need to be reported as separate SAEs and can be removed.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:40:12
User opened query 'PV Query: The discharge summary reports sepsis as a diagnosis. Please assess if this should be reported as a separate SAE.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:39:25
User opened query 'PV Query: Please provide follow up on the subject's condition since discharge.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:33:52
User opened query 'PV Query: Please provide copy of the CT scan report from 29 Oct and urine antigen and respiratory panel results from the outside hospital.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:29:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:19

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	21 Oct 2020 14:49:18

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. Subject readmitted for atrial fibrillation on 10/15-10/17; X ray on 10/15 showed pneumonia ongoing.' reason for change: New Information DataPoint Un-verified.		
	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:35:13

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:35:13

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information DataPoint Verified.		
	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:30:16

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:26:12

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: Data Entry Error		

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE. 9/29/2020 UPDATE: CONDITION IS WORSENING; SUBJECT NOW ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA, ; PLAN IS TO DO BRONCHOSCOPY; HAS HAD 2 NEG COVID TESTS. Subject's bronchoscopy was also negative for COVID, has been weaned to 3L but remains inpatient and in isolation, as cultures are still pending from bronch. Being followed by cardiology, pulmonology, and infectious disease, and is on a course of steroids.'	Heather Douds (b) (4) (b) (4)	06 Oct 2020 17:12:29

reason for change: Data Entry Error

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE. 9/29/2020 UPDATE: CONDITION IS WORSENING; SUBJECT NOW ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA, ; PLAN IS TO DO BRONCHOSCOPY; HAS HAD 2 NEG COVID TESTS.' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 19:28:58

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE.'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 16:54:27

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:26
User entered	(b) (4), (b) (6)	29 Sep 2020 13:22:22
'USA-US089-2020-mRNA-1273-P301000006'		

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:21
User closed query 'Per MM: Please confirm if the subject was evaluated for COVID-19. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:42:46
Query 'Per MM: Please confirm if the subject was evaluated for COVID-19. ' answered with 'Yes, while hospitalized. Negative. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 21:12:53
User opened query 'Per MM: Please confirm if the subject was evaluated for COVID-19. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 07:54:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 16:59:47
Data point term sent to Coder	System	28 Sep 2020 16:59:10
User entered 'Respiratory failure'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:22
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:24
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:32:50
Query 'Data is required. Please complete.' answered with 'unknown at this time, ongoing workup' (Site from System).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:59:01
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:58:50
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:27
User closed query 'Please confirm the start date. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 13:50:32
Query 'Please confirm the start date. ' answered with 'Date of diagnosis is start date, accurate as entered' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:22:02
User opened query 'Please confirm the start date. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:31:26
User entered '28 Sep 2020'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:28
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:24
DataPoint Un-verified.	Stanley Doublin (b) (4)	30 Oct 2020 18:30:09
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	30 Oct 2020 18:30:09
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:29
User entered 'Yes (Y)'	Heather Douds (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:47:04
DataPoint Un-verified.	Heather Douds (b) (4)	20 Nov 2020 19:24:05
User entered '19 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	20 Nov 2020 19:24:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:22
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:14:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data entered' (Site from Safety).	Stanley Dublin (b) (4)	30 Oct 2020 18:30:23
DataPoint Un-verified.	Stanley Dublin (b) (4)	30 Oct 2020 18:30:09
User entered '17 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	30 Oct 2020 18:30:09
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)	30 Oct 2020 14:37:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:31
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 14:26:39
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).	Cassandra Zehenny (b) (4)	20 Oct 2020 21:13:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:44:17
User entered empty.	Heather Douds (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:34
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:36
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:37
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:38
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:40
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:41
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).	(b) (4), (b) (6)	30 Sep 2020 04:32:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'unknown at this time' (Site from System).	Heather Douds (b) (4)	28 Sep 2020 16:59:07
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Sep 2020 16:58:50
User entered '1'	Heather Douds (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:43
User entered '26 Sep 2020'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:44
User closed query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:32:43
Query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:27:37
User entered '8 Oct 2020' reason for change: New Information	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:27:29
User closed query 'PV Query: Please provide the hospital discharge dates when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:09:19
Query 'PV Query: Please provide the hospital discharge dates when available.' answered with 'duplicate query; subject remains inpatient at this time, medical records to be obtained upon discharge' (Site from Safety).	Heather Douds (b) (4) (b) (4)	08 Oct 2020 13:19:24
User opened query 'PV Query: Please provide the hospital discharge dates when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:44:05
User opened query 'Per CDM: Please update the date once available. Leave this query open until the discharge date is available.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:34:39
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:46
User closed query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:32:29
Query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:27:41
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:27:29
User opened query 'Per CDM: Admitted to ICU? is Unknown. However response is needed as Yes or No. Please leave this query open until the response can be updated to Yes or No.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:33:12
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:33:02
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Unknown at this time' (Site from System).	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:59:14
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	28 Sep 2020 16:58:50
User entered 'Unknown (UNK)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:47
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:49
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:50
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:52
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:53
User entered 'Related (RELATED)' reason for change: Data Entry Error	Heather Douds (b) (4)	08 Oct 2020 19:00:14
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:55
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:56
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:19:52
User entered 'None (NONE)'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:44:58
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:00
User entered '1'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:02
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:06
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 18:14:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data entered' (Site from Safety).	Stanley Doublin (b) (4)	30 Oct 2020 18:30:37
DataPoint Un-verified.	Stanley Doublin (b) (4)	30 Oct 2020 18:30:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Stanley Doublin (b) (4)	30 Oct 2020 18:30:09
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Heather Douds (b) (4)	12 Oct 2020 20:27:29
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:44:28
User entered 'Unknown (UNKNOWN)'	Heather Douds (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:05
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:47:10
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:24:05

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	20 Nov 2020 19:24:05

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17; X RAY ON 10/15 SHOWED PNEUMONIA ONGOING. Per pulm appt 11/19, subject is recovering, 3 mon follow up going forward.' reason for change: New Information DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	28 Oct 2020 17:45:06

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	21 Oct 2020 14:49:35

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. Subject readmitted for atrial fibrillation on 10/15-10/17; X ray on 10/15 showed pneumonia ongoing.' reason for change: New Information		

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:35:42

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information		

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Heather Douds (b) (4) (b) (4)	12 Oct 2020 20:27:29

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information		

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE. 9/29/2020 UPDATE: CONDITION IS WORSENING; SUBJECT NOW ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA, ; PLAN IS TO DO BRONCHOSCOPY; HAS HAD 2 NEG COVID TESTS. Subject's bronchoscopy was also negative for COVID, has been weaned to 3L but remains inpatient and in isolation, as cultures are still pending from bronch. Being followed by cardiology, pulmonology, and infectious disease, and is on a course of steroids.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	06 Oct 2020 17:12:46

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE. 9/29/2020 UPDATE: CONDITION IS WORSENING; SUBJECT NOW ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA, ; PLAN IS TO DO BRONCHOSCOPY; HAS HAD 2 NEG COVID TESTS.' reason for change: Data Entry Error	Joan Siegner (b) (4)	29 Sep 2020 19:28:18

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. SUBJECT CONTACTED SITE AGAIN ON 9/26 WITH WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED FOR 9/28 AND URGED SUBJECT TO CONTACT PCP AND/OR SEEK OUT AN URGENT CARE CENTER. CALLED SUBJECT THIS AM (9/28) TO FOLLOW UP, SUBJECT INFORMED SITE THAT HE HAD BEEN ADMITTED TO THE HOSPITAL ON 9/26, HAD A COVID-19 SWAB THAT RESULTED NEGATIVE THIS AM (9/28), AND HAD ONGOING COUGH AND FEVER OF 101. ALSO STATED THAT HE WAS HAVING A CARDIOLOGY WORKUP DONE. SITE RECEIVED CALL FROM ID PHYSICIAN CARING FOR SUBJECT WHILE INPATIENT AND STATED THAT SUBJECT HAD PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 IN HER OPINION, AND THAT SUBJECT WAS CURRENTLY ON 6L OF O2. SUBJECT REMAINS INPATIENT AT THIS TIME, SITE WILL REQUEST RECORDS UPON DISCHARGE AND WILL UPDATE AS MORE INFORMATION BECOMES AVAILABLE.'	Heather Douds (b) (4) (b) (4)	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 16:58:50

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:49:03
User entered 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	13 Oct 2020 14:48:57

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per hospital discharge summary - new onset of cardiomyopathy/ nonischemic. Please consider adding a new safety event or updating term. Thank you! ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:58:25
User opened query 'Per hospital discharge summary - new onset of cardiomyopathy/ nonischemic. Please consider adding a new safety event or updating term. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:42:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:26
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 20:48:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Oct 2020 20:48:25
Data point term sent to Coder	System	12 Oct 2020 20:48:10
User entered 'Paroxysmal Atrial Fibrillation'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:28
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:29
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:32
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:34
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:55
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:56:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	03 Nov 2020 16:56:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:35
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Nov 2020 16:56:28
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 16:56:28
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:56:28
User entered '30 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	03 Nov 2020 16:56:28
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Nov 2020 16:55:46
User closed query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 13:19:45
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 'Event remains ongoing at this time, will provide date upon resolution' (Site from Safety).	Heather Douds (b) (4)	02 Nov 2020 16:11:45
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)	30 Oct 2020 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:37
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:38
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:40
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:41
User closed query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide site awareness date. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:53:02
Query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide site awareness date. Thank you! ' answered with '12OCT when we received medical records' (Site from CRA).	Heather Douds (b) (4) (b) (4)	19 Oct 2020 16:29:33
User opened query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide site awareness date. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:35:33
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:43
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:44
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:46
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).		12 Oct 2020 20:48:55
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	12 Oct 2020 20:47:19
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).		12 Oct 2020 20:47:19
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:47
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:49
User entered '8 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 20:48:55
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:51
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:52
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:54
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:55
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:56
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:58
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:00
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:01
User entered 'None (NONE)' reason for change: Per Query Resolution	Heather Douds (b) (4)	15 Oct 2020 14:20:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:06
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:08
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:10
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 13:34:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated. Subject in sinus rhythm based on exam during clinic visit ' (Site from Safety).	Cassandra Zehenny (b) (4)	03 Nov 2020 16:58:19
DataPoint Un-verified.	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Cassandra Zehenny (b) (4)	03 Nov 2020 16:55:46
reason for change: New Information	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:38:07
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:05
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	03 Nov 2020 16:55:46
User entered 'Subject is currently in sinus rhythm, but could intermittently go in and out of atrial fibrillation. On medication and following up with PCP to control and monitor.' reason for change: New Information	(b) (4) Cassandra Zehenny (b) (4)	03 Nov 2020 16:55:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:15
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:54:12
User closed query 'Please update with details for most recent hospitalization 15-17Oct, please list lab work, x-ray chest, resp panel, ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 17:29:43
Query 'Please update with details for most recent hospitalization 15-17Oct, please list lab work, x-ray chest, resp panel, ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 19:03:29
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	28 Oct 2020 19:03:25
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Cassandra Zehenny (b) (4)	(b) (4) 28 Oct 2020 19:03:25

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. SUBJECT READMITTED FOR ATRIAL FIBRILLATION ON 10/15-10/17; X RAY ON 10/15 SHOWED PNEUMONIA ONGOING.' reason for change: New Information		
User opened query 'Please update with details for most recent hospitalization 15-17Oct, please list lab work, x-ray chest, resp panel, ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:15:07
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:18

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	21 Oct 2020 14:48:04

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. READMITTED TO HOSPITAL 10/15-10/17 FOR ATRIAL FIBRILLATION, medications updated.' reason for change: New Information		

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	19 Oct 2020 16:14:21

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2. Readmitted to hospital 10/15-10/17 for atrial fibrillation.' reason for change: New Information		

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:36:05

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information		
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 20:48:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 20:48:55

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Cassandra Zehenny (b) (4)	(b) (4) 12 Oct 2020 20:48:55

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 20:47:19
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 20:47:19

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:50:15
User entered 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	13 Oct 2020 14:50:10

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:27
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:35:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:35:19
Data point term sent to Coder	System	12 Oct 2020 20:51:15
User entered 'Non-ST elevated myocardial infarction'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:29
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:31
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:32
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:34
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:36
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:38
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Oct 2020 13:49:44
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:40
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 13:51:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Oct 2020 13:51:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 13:49:44
User entered '26 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Oct 2020 13:49:44
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:41
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:43
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide awareness date. ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:25:02
Query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide awareness date. ' answered with '12OCT when we received medical records' (Site from CRA).	Heather Douds (b) (4) (b) (4)	19 Oct 2020 16:30:45
User opened query 'The start date is 26Sep, but event is reported as serious on 12Oct. Please provide awareness date. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:37:04
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:45
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:46
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:49
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:50
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:52
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:53
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:55
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:35:57
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:00
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:01
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:03
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:04
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:06
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:47:31
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 15:21:24
User entered 'None (NONE)' reason for change: Per	(b) (4)	
Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:36:07
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:09
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:11
User entered '1'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:13
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	13 Oct 2020 13:51:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:16
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:38
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:36:25

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:36:25

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information DataPoint Verified.		
	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:36:17

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Cassandra Zehenny (b) (4)	(b) (4) 12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.'		

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 20:50:36

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:30
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:51:24
User entered 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	13 Oct 2020 14:51:15

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:57:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:57:31
Data point term sent to Coder	System	12 Oct 2020 20:52:17
User entered 'Hypomagnesia'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:34
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:37
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:39
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:40
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:42
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:44
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:49:45
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:36:55
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	09 Nov 2020 15:36:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:36:45
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:47
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:48
User entered 'Grade 4 (Grade 4)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'The start date is 26Sep, but event is reported s serious on 12Oct. Please provide awareness date or update the start date as needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:24:18
Query 'The start date is 26Sep, but event is reported s serious on 12Oct. Please provide awareness date or update the start date as needed. ' answered with '12OCT when we received medical records' (Site from CRA).	Heather Douds (b) (4) (b) (4)	19 Oct 2020 16:31:05
User opened query 'The start date is 26Sep, but event is reported s serious on 12Oct. Please provide awareness date or update the start date as needed. ' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:38:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:50
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:52
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:53
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:55
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:57
User entered '26 Sep 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:36:58
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:00
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:02
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:03
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:05
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:06
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:08
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:09
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:47:38
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 15:22:04
User entered 'None (NONE)' reason for change: Per	(b) (4)	
Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:22:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:37:11
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:12
User entered '0'	Cassandra Zehenny (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:14
User entered '1'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:16
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:37:19
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:52
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:36:48

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:36:48

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: New Information DataPoint Verified.		
	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:37:20

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Cassandra Zehenny (b) (4)	(b) (4) 12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.'		

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 20:52:07

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:32
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:57:14
User entered 'USA-US089-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	13 Oct 2020 14:53:05

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:33
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 14:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Oct 2020 14:04:42
Data point term sent to Coder	System	13 Oct 2020 14:03:45
User entered 'Acute Kidney injury'	Heather Douds (b) (4)	13 Oct 2020 14:02:45
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:35
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:40
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:38
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:41
User entered '26 Sep 2020'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:43
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:44
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:37:23
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User closed query 'Subject was discharged from hospital on 17Oct (second hospitalization) with diagnosis AKI. Please verify if the end date should be ongoing. Thank you! ' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:37:23
Query 'Subject was discharged from hospital on 17Oct (second hospitalization) with diagnosis AKI. Please verify if the end date should be ongoing. Thank you! ' answered with 'Kidney disease ongoing from previous kidney disease, not acute' (Site from CRA).	(b) (4)	
User opened query 'Subject was discharged from hospital on 17Oct (second hospitalization) with diagnosis AKI. Please verify if the end date should be ongoing. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:29:54
DataPoint Verified.	(b) (4), (b) (6)	
User entered '8 Oct 2020'	Heather Douds (b) (4)	13 Oct 2020 14:02:45
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:48
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:49
User entered 'Grade 4 (Grade 4)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'The start date is 26Sep, but event is reported s serious on 13Oct. Please provide awareness date or update the start date as needed' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 01:35:30
Query 'The start date is 26Sep, but event is reported s serious on 13Oct. Please provide awareness date or update the start date as needed' answered with '12OCT when we received medical records' (Site from CRA).	Heather Douds (b) (4) (b) (4)	19 Oct 2020 16:31:45
User opened query 'The start date is 26Sep, but event is reported s serious on 13Oct. Please provide awareness date or update the start date as needed' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:41:04
Query 'The start date is 26Sep, but event is reported s serious on 12Oct. Please provide awareness date or update the start date as needed' canceled (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:40:52
User opened query 'The start date is 26Sep, but event is reported s serious on 12Oct. Please provide awareness date or update the start date as needed' (Site from CRA).	(b) (4), (b) (6)	18 Oct 2020 02:40:27
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:51
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:52
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:54
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:55
User entered '1'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:57
User entered '26 Sep 2020'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:38:58
User entered '8 Oct 2020'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:00
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:02
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:03
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:05
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:06
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:08
User entered 'Related (RELATED)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:09
User entered 'Not Related (NOT RELATED)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 16:42:24
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	19 Nov 2020 15:23:15
User entered 'None (NONE)' reason for change: Per	(b) (4)	
Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:23:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:39:11
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Heather Douds (b) (4)	13 Oct 2020 14:02:45
	(b) (4)	

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:13
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:14
User entered '1'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:16
User entered '0'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:19
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:48:16
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:40:10

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS (9/26 & 10/6) SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:40:10

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
BUT RESULTS NOT IN RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: Per Query Resolution DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:39:20
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 14:04:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 14:04:55

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 9/25 WITH ALLERGY SYMPTOMS (SNIFFLES, POST NASAL DRAINAGE COUGH) TYPICAL TO SUBJECT PER SUBJECT; INSTRUCTED TO CALL BACK IF ANYTHING WORSENS OR CHANGES. PER SUBJECT 9/26 WORSENING COUGH AND FEVER OF 101. ILLNESS VISIT SCHEDULED 9/28, SUBJECT URGED TO CONTACT PCP OR URGENT CARE. PER SUBJECT 9/28, ADMITTED TO THE HOSPITAL ON 9/26, HAD A NEGATIVE COVID-19 SWAB AND ONGOING COUGH AND FEVER WITH CARDIOLOGY WORKUP. PER INPATIENT ID PHYSICIAN STATED SUBJECT HAS PNEUMONIA AND RESPIRATORY FAILURE WITH CHEST X-RAY SUGGESTIVE OF COVID-19 AND IS ON 6L OF O2. 9/29 UPDATE: CONDITION WORSENING; SUBJECT ON 8L/MIN O2; DIFFUSE BILAT INFILTRATES, POSSIBLY ORGANIZING PNEUMONIA; BRONCHOSCOPY PLANNED, HAS HAD 2 NEG COVID TESTS. SUBJECT'S BRONCHOSCOPY ALSO NEGATIVE FOR COVID, WEANED TO 3L, REMAINS INPATIENT, CULTURES ARE STILL PENDING FROM BRONCH. BEING FOLLOWED BY CARDS, PULM, AND ID, ON STEROIDS. UPDATE 10/12: SUBJECT DISCHARGED 10/8 ON 2L O2. DIAGNOSED WITH NSTEMI ON ADMISSION IN NEW ONSET AFIB; HOLTER MONITOR ON DISCHARGE FOR 30 DAYS. ECHO SHOWS EF OF 35-45% AT DISCHARGE. TROPONINS ELEVATED ON ADMISSION, SECONDARY TO ISCHEMIA RELATED TO AFIB PER RECORDS. CHEST X RAYS SHOW BILAT INFILTRATES/MULTIFOCAL PNEUMONIA; CHEST CT WITH SAME FINDINGS - FINAL DIAGNOSIS OF CRYPTOGENIC ORGANIZING PNEUMONIA, REMAINS ON PREDNISONE. NEGATIVE RESPIRATORY PANEL. BRONCHOSCOPY 9/30, CULTURES OBTAINED BUT RESULTS NOT IN	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:04:55

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
RECORDS. PER SUBJECT REPORT AS OF 10/12, NOW ON 4L O2.' reason for change: Per Query Resolution		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 14:02:45
User entered empty.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 14:02:45

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:46:45
Data point term sent to Coder	System	19 Oct 2020 14:45:09
User entered 'nausea'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:13
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:12
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:10
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:08
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:06
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:04
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:03
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:59
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:56
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:55
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:53
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:49
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:47
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:46
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:44
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:42
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:41
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:39
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:37
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:11:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:11:27
User entered 'Related (RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:11:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:44:27
User entered empty.	Stanley Doublin (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:35
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:11:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:11:27
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:11:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:44:27
User entered empty.	Stanley Doublin (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there are multiple records recorded with IP Withdrawal. There should be only 1 record as such and should be the event causing IP withdrawal. Please reconcile and make all appropriate updates.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 12:16:18
Query 'Per CDM: it appears there are multiple records recorded with IP Withdrawal. There should be only 1 record as such and should be the event causing IP withdrawal. Please reconcile and make all appropriate updates.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	22 Nov 2020 16:13:57
User entered 'None (NONE)' reason for change: New Information	Cassandra Zehenny (b) (4)	19 Nov 2020 15:20:02
User opened query 'Per CDM: it appears there are multiple records recorded with IP Withdrawal. There should be only 1 record as such and should be the event causing IP withdrawal. Please reconcile and make all appropriate updates.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 09:19:45
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 21:11:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 21:11:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Cassandra Zehenny (b) (4)	20 Oct 2020 21:11:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 14:44:27
User entered empty.	Stanley Dublin (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Oct 2020 16:32:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Oct 2020 14:44:27
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:29
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	19 Oct 2020 16:32:03
User entered '0'	(b) (4) Stanley Dublin (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:27
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:24
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:43:22
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 14:44:27

US3552232

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 26 Nov 2020 09:37:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:44:27

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:41
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:02:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Tylenol, Hydrocodone, trazodone, Voltaren, Amaryl, Apresoline, Flomax, per PCP notes. ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 04:14:35
Query 'Please add Tylenol, Hydrocodone, trazodone, Voltaren, Amaryl, Apresoline, Flomax, per PCP notes. ' answered with 'Dates unknown; con meds currently up to date per discharge instructions. Medical records request placed for medications during hospitalization.' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 14:23:52
User opened query 'Please add Tylenol, Hydrocodone, trazodone, Voltaren, Amaryl, Apresoline, Flomax, per PCP notes. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:14:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 13:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 13:55:35
Data point term sent to Coder	System	13 Oct 2020 13:54:28
Coding entries removed.	Heather Douds (b) (4)	13 Oct 2020 13:53:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Aug 2020 20:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Aug 2020 20:28:41
Data point term sent to Coder	System	29 Aug 2020 20:27:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Lantus' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 20:26:51
Data point term sent to Coder	System	29 Aug 2020 19:04:03
User entered 'insulin'	Mikayla Frye (b) (4)	29 Aug 2020 19:03:07
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'TYPE 2 DIABETES' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Oct 2020 13:53:28
User entered 'type 1 diabetes'	(b) (4)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:03:07
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '25' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:16:06
User entered '30'	Mikayla Frye (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'U'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2018'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:03:07

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add meds administered during hospitalization (PCR notes page 19). ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 04:15:19
Query 'Please add meds administered during hospitalization (PCR notes page 19). ' answered with 'Medical records request placed, awaiting records' (Site from CRA).	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:24:09
User opened query 'Please add meds administered during hospitalization (PCR notes page 19). ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:20:26
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:55:35
Data point term sent to Coder	System	13 Oct 2020 13:54:28
Coding entries removed.	Heather Douds (b) (4) (b) (4)	13 Oct 2020 13:53:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:42:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:42:42
Data point term sent to Coder	System	29 Aug 2020 19:04:04
User entered 'victoza'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'TYPE 2 DIABETES' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Oct 2020 13:53:54
User entered 'type 1 diabetes'	(b) (4)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:03:37
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '1.8'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2017'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:03:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please capture procedures performed during hospitalization , inclusive of CT chest, CXR (26Sep and 06Oct), bronchoscopy ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:26:38
Query 'Please capture procedures performed during hospitalization , inclusive of CT chest, CXR (26Sep and 06Oct), bronchoscopy ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 14:24:44
User opened query 'Please capture procedures performed during hospitalization , inclusive of CT chest, CXR (26Sep and 06Oct), bronchoscopy ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:26:18
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:05:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 19:05:46
Data point term sent to Coder	System	29 Aug 2020 19:05:04
User entered 'plavix'	Mikayla Frye (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'coronary artery disease'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0.5'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:16:33
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '08 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:16:33
User entered empty.	Mikayla Frye (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:04:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 20:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 20:28:41
Data point term sent to Coder	System	29 Aug 2020 20:28:11
Data point term sent to Coder	System	29 Aug 2020 19:05:04
User entered 'hydralazine'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'hypertension'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 20:27:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 20:27:16
User entered '50' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 20:27:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:04:45
User entered empty.	Mikayla Frye (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 20:27:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 20:27:16
User entered 'mg (mg)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 20:27:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:04:45
User entered empty.	Mikayla Frye (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 20:27:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 20:27:16
User entered 'once daily (QD)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 20:27:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:04:45
User entered empty.	Mikayla Frye (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 20:27:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 20:27:16
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	29 Aug 2020 20:27:16
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:04:45
User entered empty.	Mikayla Frye (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un Feb 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 20:27:16
User entered empty.	System	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 20:27:16
User entered empty.	System	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 20:27:16
User entered empty.	System	29 Aug 2020 19:04:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: TAMULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:46
Data point term sent to Coder	System	29 Aug 2020 19:06:05
User entered 'tamulosin'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'urinary retention'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0.4'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un Feb 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:05:26

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Aug 2020 05:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	30 Aug 2020 05:52:45
Data point term sent to Coder	System	29 Aug 2020 19:06:08
User entered 'finasteride'	Mikayla Frye (b) (4)	29 Aug 2020 19:06:06
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'benign prostatic hypertension'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '5'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un Nov 2019'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:06:06

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:47
Data point term sent to Coder	System	29 Aug 2020 19:07:11
User entered 'amlodipine'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'coronary artery disease'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '10'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Aug 2020 19:06:37
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:45:36
User entered '15 Oct 2020' reason for change: New Information	(b) (4)	21 Oct 2020 14:45:36
DataPoint Verified.	Mikayla Frye (b) (4)	14 Oct 2020 16:06:12
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:06:37

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:57:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:57:32
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	13 Oct 2020 13:56:31 13 Oct 2020 13:56:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:07:48
Data point term sent to Coder User entered 'metformin'	System Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:11 29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'TYPE 2 DIABETES' reason for change: Data Entry Error	Heather Douds (b) (4)	13 Oct 2020 13:56:12
User entered 'type 1 diabetes'	(b) (4)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:07:10
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '1000'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'twice daily (BID)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2015'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:17:24
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	12 Oct 2020 21:17:24
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	29 Aug 2020 19:07:10
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:07:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:08:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:08:48
Data point term sent to Coder	System	29 Aug 2020 19:08:11
User entered 'atorvastatin'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'hyperlipidemia'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '80'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2015'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:07:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:09:49
Data point term sent to Coder	System	29 Aug 2020 19:09:12
User entered 'aspirin'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'coronary artery disease'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '81'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2013'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:08:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:10:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:10:38
Data point term sent to Coder	System	29 Aug 2020 19:10:13
User entered 'trazadone'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'insomnia'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '50'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'un UNK 2010'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 19:09:14

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE, PRODUCTSYNONYM: CORICIDIN II COUGH - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:54:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:54:35
Data point term sent to Coder	System	21 Oct 2020 14:26:53
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	21 Oct 2020 14:26:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	14 Oct 2020 16:06:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE, PRODUCTSYNONYM: CORICIDIN II COUGH - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:52:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:52:17
Data point term sent to Coder	System	29 Sep 2020 14:47:14
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	29 Sep 2020 14:47:07
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated per query request' (Site from System).	Heather Douds (b) (4) (b) (4)	29 Sep 2020 14:47:07
Data point term sent to Coder	System	29 Sep 2020 14:43:01
v6.020 DTW (1102)		2061 of 3042

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CORICIDIN [dextromethorphan/chloropheniramine maleate]' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	29 Sep 2020 14:42:29
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:42:45
Data point term sent to Coder	System	25 Sep 2020 17:28:41
User entered 'coricidin'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	21 Oct 2020 14:26:03
User entered 'SEASONAL ALLERGIES/nasal congestion' reason for change: New Information	(b) (4)	
DataPoint Verified.	Cassandra Zehenny (b) (4)	21 Oct 2020 14:26:03
	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'seasonal allergies'	Stanley Dublin (b) (4)	25 Sep 2020 17:28:05
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:34:38
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'exact dosage unknown, self reported by subject' (Site from DM).	Heather Douds (b) (4)	02 Nov 2020 16:13:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 03:34:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '1'	Stanley Doublin (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'tablet (TABLET)'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '22 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:17:55
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '26 Sep 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	12 Oct 2020 21:17:55
User entered empty.	Stanley Doublin (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 17:28:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Please check spelling - Amniodarone' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:28:00
User opened query 'Please check spelling - Amniodarone' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:27:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 21:22:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 21:22:18
Data point term sent to Coder	System	12 Oct 2020 21:21:05
User entered 'Amiodarone'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'paroxysmal Atrial fibrillation'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '200'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User closed query 'Per source, start date - 06Oct. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Query 'Per source, start date - 06Oct. Please reconcile ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 18:39:57
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	28 Oct 2020 18:39:53
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:39:53
	(b) (4)	
User opened query 'Per source, start date - 06Oct. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:28:32
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
	(b) (4)	
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:20:54
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 21:20:54

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 22:49:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 22:49:25
Data point term sent to Coder	System	12 Oct 2020 21:23:08
User entered 'Apixaban'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Paroxysmal atrial fibrillation'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '5'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:09
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:15
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:22:08
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 21:22:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 00:21:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 00:21:25
Data point term sent to Coder	System	12 Oct 2020 21:24:11
User entered 'Prednisone'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Pneumonia'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '40'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:14
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:24
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
	(b) (4)	
User entered '2 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:23:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:28:52
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:23:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:28:54
DataPoint Un-verified.	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
User entered '15 Oct 2020' reason for change: New Information	(b) (4)	
	Mikayla Frye (b) (4)	21 Oct 2020 14:46:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4)	12 Oct 2020 21:23:23
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 21:23:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:20:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 21:31:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 21:31:36
Data point term sent to Coder	System	12 Nov 2020 21:30:12
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'data entry error, prescribed for atrial fibrillation' (Site from DM).	Cassandra Zehenny (b) (4)	12 Nov 2020 21:29:39
Coding entries removed.	Cassandra Zehenny (b) (4)	12 Nov 2020 21:29:11
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:21:09
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 21:25:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Oct 2020 21:25:23
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	12 Oct 2020 21:24:12
User entered 'Metoprolol XL'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:02
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 19:57:53
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	12 Nov 2020 21:29:11
User entered 'Atrial Fibrillation' reason for change:	(b) (4)	
Data Entry Error	Cassandra Zehenny (b) (4)	12 Nov 2020 21:29:11
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Hypertension'	(b) (4)	
	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:02
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '200'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:30
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:02
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 21:24:02

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:26:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:26:24
Data point term sent to Coder	System	12 Oct 2020 21:25:13
User entered 'Effexor XR'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Depression'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '150'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'mg (mg)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:22
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:36
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '8 Oct 2020'	Cassandra Zehenny (b) (4)	12 Oct 2020 21:24:36
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:06:12
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Oct 2020 21:24:36

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:57:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:57:38
Data point term sent to Coder	System	19 Oct 2020 14:50:21
User entered 'aspirin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'non-st elevated myocardial infarction'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '324'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:49:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:30:42
Data point term sent to Coder	System	19 Oct 2020 14:53:28
User entered 'rocephin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2000'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 14:53:25

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:57:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:57:59
Data point term sent to Coder	System	19 Oct 2020 14:54:31
User entered 'azithromycin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '250'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
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).	System	19 Oct 2020 14:54:30
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).	System	19 Oct 2020 14:54:30
User entered 'once daily (QD)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Oct 2020 14:54:30
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).	System	19 Oct 2020 14:54:22
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:54:30
User entered empty.	System	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 14:54:30
User entered empty.	System	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 14:54:30
User entered empty.	System	19 Oct 2020 14:54:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:41:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:41:05
Data point term sent to Coder	System	16 Nov 2020 13:57:44
Coding entries removed.	Heather Douds (b) (4) (b) (4)	16 Nov 2020 13:57:18
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	28 Oct 2020 18:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:19:40
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 Oct 2020 15:19:40
Data point term sent to Coder	System	19 Oct 2020 14:55:35
User entered 'magnesium'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:52:29
User closed query 'Please check spelling hypomagnesia ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 15:52:16
Query 'Please check spelling hypomagnesia ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	16 Nov 2020 13:57:24
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	16 Nov 2020 13:57:18
	(b) (4)	
User entered 'HYPOMagnesia' reason for change:	Heather Douds (b) (4)	16 Nov 2020 13:57:18
Data Entry Error	(b) (4)	
User opened query 'Please check spelling hypomagnesia ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 20:07:33
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
	(b) (4)	
User entered 'hypomeynesia'	Stanley Dublin (b) (4)	19 Oct 2020 14:55:29
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'g (g)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:55:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:22:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:22:37
Data point term sent to Coder	System	19 Oct 2020 14:57:40
User entered 'norco [hydrocodone/acetaminophen]'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5/325'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:34
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:53
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:15:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 14:57:10
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:57:10

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
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 (b) (4) (b) (4)	19 Oct 2020 14:59:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 14:59:39
Data point term sent to Coder	System	19 Oct 2020 14:58:41
User entered 'ondansetron'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'nausea'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '4'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 14:58:18

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:17:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:17:16
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 CORONARY ARTERY DISEASE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:25:32
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 CORONARY ARTERY DISEASE should be recorded, and update con med indication or provide clarification. ' answered with 'updated ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	12 Nov 2020 21:30:19
Data point term sent to Coder	System	12 Nov 2020 21:30:15
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	12 Nov 2020 21:30:13
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 CORONARY ARTERY DISEASE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:36
Data point term sent to Coder	System	19 Oct 2020 15:00:45
User entered 'lovenox'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 20:08:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Oct 2020 15:00:05
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 20:08:09
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
User entered 'coagulation prophylaxis' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	12 Nov 2020 21:30:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'coronary artery disease'	Stanley Doublin (b) (4)	19 Oct 2020 15:00:05
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '80'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:00:05

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:03:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:03:35
Data point term sent to Coder	System	19 Oct 2020 15:02:48
User entered 'tessalon'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'cough'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '200'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'as needed (PRN)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:01:52

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:05:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:05:40
Data point term sent to Coder	System	19 Oct 2020 15:04:55
User entered 'novolog'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'type 2 diabetes'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0-5'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'units'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'every 4 hours'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:45
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:06
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:04:30
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:04:30

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:07:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:07:01
Data point term sent to Coder	System	19 Oct 2020 15:05:57
User entered 'aspirin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'acute coronary syndrome'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '81'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:50
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:13
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:05:29
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:05:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:16:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:16:22
Data point term sent to Coder	System	19 Oct 2020 15:09:04
User entered 'decadron'	Stanley Doublin (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '6'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '26 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '27 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:08:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:11:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:11:37
Data point term sent to Coder	System	19 Oct 2020 15:10:06
User entered 'levaquin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '750'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '28 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:09:29

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:22:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:22:36
Data point term sent to Coder	System	19 Oct 2020 15:12:07
User entered 'mucinex DM [Dextromethorphan/Guaifenesin]'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30/600'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'twice daily (BID)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '29 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:10:58
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:31
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:11:48
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:11:48

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:45:27
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 Oct 2020 02:45:27
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Data point term sent to Coder	System	28 Oct 2020 18:40:33
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:40:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:36:34
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 Oct 2020 15:36:34
Data point term sent to Coder	System	19 Oct 2020 15:14:09
User entered 'albuterol 0.5%'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'bronchoscopy'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2.5'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:20
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:48:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:25
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:20
User opened query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:52:40
User entered 'inhalation'	Stanley Doublin (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:14:01

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANESTHETICS, LOCAL, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:32:32
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 Nov 2020 10:32:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Data point term sent to Coder	System	28 Oct 2020 18:41:36
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:40:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:35
Data point term sent to Coder	System	19 Oct 2020 15:16:14
User entered 'lidocaine 4%'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'bronchoscopy'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1.5'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mL (mL)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:42
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:48:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:45
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:40:42
User opened query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:53:17
User entered 'inhalation'	Stanley Doublin (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:15:23

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:18:36
Data point term sent to Coder	System	19 Oct 2020 15:17:17
User entered 'lovenox'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'coronary artery disease'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '40'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:48
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (b) (4)	19 Oct 2020 15:16:44
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:08
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:48
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:16:44
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:16:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL, PRODUCTSYNONYM: LEVALBUTEROL [LEVOSALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:25:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:25:31
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	28 Oct 2020 18:58:45
Data point term sent to Coder	System	28 Oct 2020 18:41:46
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	28 Oct 2020 18:41:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL, PRODUCTSYNONYM: LEVALBUTEROL [LEVOSALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:33:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:33:35
Data point term sent to Coder	System	19 Oct 2020 15:18:18
User entered 'levalbuterol'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '.63'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'EVERY 6 HOURS' reason for change:	Cassandra Zehenny (b) (4)	28 Oct 2020 18:41:12
Data Entry Error	(b) (4)	
User entered 'every 6 houtd'	Stanley Dublin (b) (4)	19 Oct 2020 15:17:44
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:41:12
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:48:59
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
Query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 18:41:15
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 18:41:12
User opened query 'Per CDM: The ROA "INHALATION" is one of the listed choices of ROA. Kindly, update the data field and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:54:01
User entered 'inhalation'	Stanley Doublin (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:12
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:54
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:16:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:17:44
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:17:44

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:17:22
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 Oct 2020 16:17:22
Data point term sent to Coder	System	19 Oct 2020 15:19:22
User entered 'diltiazem'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '10'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:01
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (b) (4)	19 Oct 2020 15:18:47
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:01
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '1 Oct 2020'	Stanley Dublin (b) (4)	19 Oct 2020 15:18:47
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:18:47

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:16:22
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 Oct 2020 16:16:22
Data point term sent to Coder	System	19 Oct 2020 15:20:23
User entered 'digoxin'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '.5'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:21
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	19 Oct 2020 15:19:42
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:22
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:17:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:19:42
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:19:42

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:07:34
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 Oct 2020 16:07:34
Data point term sent to Coder	System	19 Oct 2020 15:21:26
User entered 'amiodarone'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '150'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:26
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:05
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:20:34
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:27
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:05
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:20:34
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:20:34

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:07:34
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 Oct 2020 16:07:34
Data point term sent to Coder	System	19 Oct 2020 15:22:28
User entered 'amiodarone'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'PAROXYSMAL ATRIAL FIBRILLATION'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '450'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'continuous'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:31
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	19 Oct 2020 15:21:51
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:33
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '6 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:21:51
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:21:51

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:33:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:33:35
Data point term sent to Coder	System	19 Oct 2020 15:22:28
User entered 'lasix'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '20'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:36
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:22:22
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:38
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	19 Oct 2020 15:22:22
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:22:22

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:49:35
Data point term sent to Coder	System	21 Oct 2020 14:48:31
User entered 'tessalon'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'cough'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '100'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'every 8 hours'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:21:54
DataPoint Un-verified.	Heather Douds (b) (4)	23 Nov 2020 19:47:49
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	23 Nov 2020 19:47:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:21:55
DataPoint Un-verified.	Heather Douds (b) (4)	23 Nov 2020 19:47:49
User entered '20 Nov 2020' reason for change: New Information	(b) (4)	23 Nov 2020 19:47:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:48:09

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:50:40
Data point term sent to Coder	System	21 Oct 2020 14:49:34
User entered 'prednisone'	Mikayla Frye (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '30'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '17 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	26 Oct 2020 12:55:28
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '24 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	26 Oct 2020 12:55:28
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	21 Oct 2020 14:48:39
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:48:39

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:51:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:51:43
Data point term sent to Coder	System	21 Oct 2020 14:50:36
User entered 'diltiazem'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '19'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:50:17

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:52:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:52:46
Data point term sent to Coder	System	21 Oct 2020 14:51:40
User entered 'diltiazem'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '125'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'continuous'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:51:08

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:54:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:54:50
Data point term sent to Coder	System	21 Oct 2020 14:53:42
User entered 'amiodarone'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '150'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once (ONCE)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:52:46

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:55:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:55:41
Data point term sent to Coder	System	21 Oct 2020 14:54:44
User entered 'amiodarone'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'paroxysmal atrial fibrillation'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '450'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'continuous'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Intravenous (INTRAVENOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:53:53

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:35:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:35:34
Data point term sent to Coder	System	21 Oct 2020 14:54:45
User entered 'lovenox'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'coronary artery disease'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '80'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'twice daily (BID)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '15 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '17 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:54:38

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:57:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:57:40
Data point term sent to Coder	System	21 Oct 2020 14:56:48
User entered 'novolog'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'diabetes type 2'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '2-12'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'units'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'other (OTHER)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'every 4 hours'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '16 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '17 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:49

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Please update conmed log to reflect all meds given during hospitalon on 15-17Oct. Thank you! ' canceled (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:59:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User opened query 'Please update conmed log to reflect all meds given during hospitalon on 15-17Oct. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:09:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:56:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 12:56:31
Data point term sent to Coder	System	26 Oct 2020 12:55:44
User entered 'prednisone'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'pneumonia'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '20'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '25 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered '0'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:59
DataPoint Un-verified.	Heather Douds (b) (4)	04 Nov 2020 17:26:16
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Heather Douds (b) (4)	04 Nov 2020 17:26:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	26 Oct 2020 12:54:55
	(b) (4)	

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:12:00
User entered '01 Nov 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	11 Nov 2020 17:18:44
DataPoint Un-verified.	Heather Douds (b) (4)	04 Nov 2020 17:26:16
User entered '1 Nov 2020' reason for change: New Information	Heather Douds (b) (4)	04 Nov 2020 17:26:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered empty.	Stanley Dublin (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:58:45
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 26 Nov 2020 09:37:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 12:54:55

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:37:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:59:37
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:24:49

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:38

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:54:08
User entered '30 Sep 2020'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:27:11

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:54:08
User entered 'Bronchoscopy'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:27:11

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:54:08
User entered 'Diagnostic (DIAGNOSTIC)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:27:11

US3552232

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:37:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:54:08
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 14:27:11

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:38

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Oct 2020'	Heather Douds (b) (4) (b) (4)	08 Oct 2020 13:02:25

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Please update to SAE' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:26:54
Query 'Please update to SAE' answered with 'Updated' (Site from CRA).	Cassandra Zehenny (b) (4)	13 Oct 2020 15:38:26
User entered 'SAE (specify) (SAE)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	13 Oct 2020 15:38:22
User opened query 'Please update to SAE' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 02:36:58
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4)	08 Oct 2020 13:02:25
	(b) (4)	

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
User closed query ' SAE respiratory failure is listed as reason for IP withdrawal. This event's line number is 3. Please considering to update to SAE#3. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:19:47
Query ' SAE respiratory failure is listed as reason for IP withdrawal. This event's line number is 3. Please considering to update to SAE#3. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:37:52
User entered 'SAE #3' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	23 Nov 2020 15:37:38
User opened query ' SAE respiratory failure is listed as reason for IP withdrawal. This event's line number is 3. Please considering to update to SAE#3. ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:17:03
User closed query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:19:59
Query 'Per CDM: Please record SAE record number instead of details ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:38:51
User entered 'SAE #2' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 17:38:48
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:16:10
User closed query 'PAROXYSMAL ATRIAL FIBRILLATION indicated as reason for IP withdrawal. Please update the entry. ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 23:27:15
Query 'PAROXYSMAL ATRIAL FIBRILLATION indicated as reason for IP withdrawal. Please update the entry. ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 14:19:21
User opened query 'PAROXYSMAL ATRIAL FIBRILLATION indicated as reason for IP withdrawal. Please update the entry. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:32:22
User closed query 'Please enter single SAE , term must match the SAE description. Also please update the AE eCRF for corresponding SAE to indicate that Investigational Product was withdrawn. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:26:56
User entered 'RESPIRATORY FAILURE' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	13 Oct 2020 15:39:41
v6.020 DTW (1102)		2737 of 3042

US3552232

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:37:38

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

Audit	User	Time (GMT)
Query 'Please enter single SAE , term must match the SAE description. Also please update the AE eCRF for corresponding SAE to indicate that Investigational Product was withdrawn. ' answered with 'reason is correct as stated. ' (Site from CRA). User opened query 'Please enter single SAE , term must match the SAE description. Also please update the AE eCRF for corresponding SAE to indicate that Investigational Product was withdrawn. ' (Site from CRA). User entered 'Pneumonia, respiratory failure'	Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	13 Oct 2020 15:39:20 13 Oct 2020 02:39:27 08 Oct 2020 13:02:25

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:53
User entered '29/Sep/2020 09:22'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:59
User entered '30/Sep/2020 13:12'	System	30 Sep 2020 13:12:12

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:01
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 12:13:31
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 13:12:12

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:06
User entered '07/Oct/2020 08:13'	System	07 Oct 2020 12:13:39

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:09:49
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 12:13:39

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:13
User entered '09/Oct/2020 13:09'	System	09 Oct 2020 13:10:02

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:15
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:57:46
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 13:10:02

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:20
User entered '13/Oct/2020 14:57'	System	13 Oct 2020 14:58:04

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:11:03
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 14:58:04

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:25
User entered '15/Oct/2020 20:11'	System	16 Oct 2020 00:11:14

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 11:41:02
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 00:11:14

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:30
User entered '16/Oct/2020 07:41'	System	16 Oct 2020 11:41:14

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:31
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 13:38:02
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 11:41:14

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:35
User entered '20/Oct/2020 13:38'	System	20 Oct 2020 13:38:44

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:38
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 13:39:15
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 13:38:44

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:42
User entered '21/Oct/2020 14:28'	System	21 Oct 2020 14:28:56

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:44
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 15:46:02
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 14:28:56

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:49
User entered '22/Oct/2020 15:47'	System	22 Oct 2020 15:47:58

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:51
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:12:29
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 15:47:58

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:55
User entered '29/Oct/2020 11:12'	System	29 Oct 2020 15:12:46

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:45:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:15:09
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 15:12:46

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:46:01
User entered '02/Nov/2020 13:15'	System	02 Nov 2020 18:15:24

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (12)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:46:04
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 13:34:30
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 18:15:24

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:46:08
User entered '04/Nov/2020 13:34'	System	04 Nov 2020 13:34:47

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (13)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:46:10
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 13:34:47

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:47
User entered '10/Nov/2020 20:25'	System	10 Nov 2020 20:25:24

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (14)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:48
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 20:25:24

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:33
User entered '20/Nov/2020 18:03'	System	20 Nov 2020 18:03:54

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (15)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:34
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 18:03:54

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:41
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'USA-US089-2020-MRNA-1273-P301000006'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:43
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:44
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:46
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:47
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'Yes (Y)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'No (N)'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:57
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'sharon'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:51:59
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'frey'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:16
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:04
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:43
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:18
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:08
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:41
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:22:45
User entered 'MO'	System	29 Sep 2020 13:21:32

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:19
Un-reviewed for Safety.	System	20 Nov 2020 18:03:54
DataPoint Un-verified.	System	20 Nov 2020 18:03:54
User entered empty.	System	20 Nov 2020 18:03:54
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 18:03:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:32:10
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:22:20
Un-reviewed for Safety.	System	10 Nov 2020 20:25:24
DataPoint Un-verified.	System	10 Nov 2020 20:25:24
User entered empty.	System	10 Nov 2020 20:25:24
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 20:24:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:29:45
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:30

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:52:10
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:11:57
User entered 'US'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	23 Nov 2020 14:17:31
User entered '15'	System	20 Nov 2020 18:03:54
User entered '14'	System	10 Nov 2020 20:25:24
User entered '13'	System	04 Nov 2020 13:34:47
User entered '12'	System	02 Nov 2020 18:15:24
User entered '11'	System	29 Oct 2020 15:12:46
User entered '10'	System	22 Oct 2020 15:47:58
User entered '9'	System	21 Oct 2020 14:28:56
User entered '8'	System	20 Oct 2020 13:38:44
User entered '7'	System	16 Oct 2020 11:41:14
User entered '6'	System	16 Oct 2020 00:11:14
User entered '5'	System	13 Oct 2020 14:58:04
User entered '4'	System	09 Oct 2020 13:10:02
User entered '3'	System	07 Oct 2020 12:13:39
User entered '2'	System	30 Sep 2020 13:12:12
User entered '1'	System	29 Sep 2020 13:22:52

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Generated On: 26 Nov 2020 09:37:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:38
User entered '23/Nov/2020 14:17'	System	23 Nov 2020 14:17:31

US3552232

Folder: SAE USA-US089-2020-MRNA-1273-P301000006

Form: Safety Report Form (16)

Generated On: 26 Nov 2020 09:37:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:55:40
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 14:17:31